Exhibit 1

BSF | BOIES SCHILLER FLEXNER

November 16, 2017

VIA E-MAIL AND FEDEX

The Honorable Eric D. Hargan
Acting Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Email: Eric.Hargan@hhs.gov

Re: Miriam Holman

Dear Secretary Hargan:

This firm represents Miriam Holman, a 21-year-old woman who is currently on an artificial lung machine in the intensive care unit at Columbia University Medical Center in New York (CUMC). The issues raised in this letter are of utmost urgency and are literally a matter of life and death. We request that you give this letter your immediate attention so that you can either grant our request or we can seek immediate emergency judicial relief.

Request: We request that you take immediate action and direct the Organ Procurement and Transportation Network (OPTN) to set aside those portions of OPTN Policy 10 that require donor lungs to first be made available to candidates within the OPTN's local Donor Service Areas (DSAs) irrespective of a candidate's medical priority.

Under OPTN policy, organs are to be prioritized among potential candidates by medical priority. With regard to lungs, medical priority is determined by a candidate's Lung Allocation Score (LAS) which is a priority ranking of 1 to 100.

The OPTN has 58 Organ Procurement Organizations, or OPOs, throughout the United States, each of which serves within the bounds of its DSA. OPTN's current policy provides that when a lung becomes available it is first made available to candidates within the local DSA even if there are candidates with a higher medical priority, i.e., a higher LAS, within range of the lung or even closer. By prioritizing lungs to the local OPO, OPTN limits the number of lungs available to high priority transplant candidates like Miriam and effectively allocates available lungs based on a candidate's place of residence instead of medical priority. This policy is in direct contravention of the OPTN's legislative mandate which requires allocation based on medical priority.

By way of example, Miriam has an LAS of 91, which indicates an extremely high level of medical need for a transplant and puts her in the top 1% of patients awaiting

lungs based on that measure. Miriam is registered as a candidate at CUMC, which is located in the DSA for southeastern New York. That DSA is serviced by LiveOnNY, the DSA's OPO. If a pair of lungs suitable for Miriam became available from a donor in Fort Lee, New Jersey (a stone's throw from CUMC), the lung would be offered first to all suitable candidates in the DSA encompassing Northern and Central New Jersey, where Fort Lee is located, regardless of whether those candidates' LAS were higher or lower than Miriam's. Moreover, that candidate would likely be *geographically further away* from the donated lung than Miriam.

Miriam is not looking for any special treatment. She is only asking that you exercise your authority to set aside an antiquated and inflexible policy established by a federally-created organization supervised by your Department, so that Miriam can be considered for available lungs based on her medical priority without regard for arbitrary geographical boundaries.

Authority: The Secretary has the authority to direct United Network for Organ Sharing (UNOS) and OPTN to take action under 42 C.F.R. 121.4(d)(2) and (3). Those provisions provide the Secretary with authority to "[d]irect the OPTN to revise the policies or practices consistent with the Secretary's response to the comments" or "[t]ake such other action as the Secretary determines appropriate." The Secretary also has authority to vary OPTN policies on a limited basis under 42 C.F.R. 121.8(g).

Background

1. Miriam Holman

Miriam is a 21-year-old woman with pulmonary hypertension, which is a type of high blood pressure that affects the arteries in one's lungs. Pulmonary hypertension can be treated but is generally not curable. Miriam has a family history of pulmonary hypertension. Miriam's sister passed away from pulmonary hypertension at the age of 10, about 13 years ago.

Miriam was first diagnosed with pulmonary hypertension in 2014, while studying abroad. Over the last three years she has been in and out of hospitals and has undergone various procedures. She has been under constant medical attention as the pulmonary hypertension has caused loss of consciousness and seizures.

Miriam has been in the medical intensive care unit at CUMC since September 24, 2017, and was listed for a lung transplant on October 6, 2017. She is waitlisted for a lung at CUMC, which is in the DSA for southeastern New York. As stated above, Miriam has an LAS of 91, which puts her in the top 1% of patients awaiting an organ based on the urgency of her medical need. On any given day her LAS would more likely than not put her at the *very top* of the list for her blood type in the DSA for southeastern New York.

2. OPTN and UNOS

The National Organ Transplant Act of 1984 (NOTA) created the OPTN. The current version of NOTA is codified at 42 U.S.C. § 274, which provides that the Secretary must establish and operate the OPTN in accordance with the requirements of NOTA.

NOTA empowers the Secretary of the Department of Health and Human Services (HHS) to contract with UNOS, a non-profit private organization, to operate the OPTN. The Secretary contracts with UNOS through the Health Resources and Services Administration (HRSA). The Secretary has also promulgated regulations that govern the OPTN (42 C.F.R § 121). These regulations provide, among other things, that OPTN's Board of Directors shall be responsible for developing policies for the operation of the OPTN, including "[p]olicies for the equitable allocation of cadaveric organs in accordance with §121.8." 42 C.F.R. §121.4(a)(1).

Section 121.8(a) provides as follows:

(a) ***Policy development.*** The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of

the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

42 C.F.R. §121.8(a) (emphasis added).

NOTA and regulations promulgated thereunder clearly require that OPTN policies for organ allocation be equitable, that they provide for organ allocation based on medical severity, and that they *not* base organ allocation on a candidate's place of residence or listing. Miriam does not seek special treatment. She only asks for the equitable treatment that she is entitled to under the law, based on the sound medical judgment of her doctors.

3. OPTN's Lung Allocation Policy Unfairly Allocates Lungs Based on Geography

The OPTN rules for allocation of lungs are set forth in OPTN Policy 10 (Allocation of Lungs) (Exhibit A).

Policy 10.1 (Priorities and Score Assignments for Lung Candidates) provides that lung candidates less than 12 years old "are assigned a priority for lung allocation that is based on medical urgency." Lung candidates 12 years or older "use a Lung Allocation Score (LAS) to determine lung allocation, as well as geography and blood type." Policy 10.4.C. (Allocation of Lungs from Deceased Donors at Least 18 Years Old) governs the allocations of adult lungs.

Under Policy 10.4.C., as set forth in Table 10-9, adult lungs are matched with candidates using a two-factor ranking system: geographic location and medical priority. Table 10-9 provides six geographic rankings and six medical rankings for the allocation of lungs, which creates 36 different priority levels in all.

Geographic Ranking: ***Prior to the application of any medical priority ranking***, OPTN Policy limits the availability of lungs by geography based on the candidate's place of residence or place of listing. The ranking is as follows:

1st: Within the donor's organ procurement organization (OPO) donation service area (DSA).

2nd: Zone A. Zone A includes all transplant hospitals that are within 500 nautical miles of the donor hospital but outside of the donor hospital's DSA.

3rd: Zone B. Zone B includes all transplant hospitals that are within 1,000 nautical miles of the donor hospital but outside of Zone A and the donor hospital's DSA.

4th: Zone C. Zone C includes all transplant hospitals that are within 1,500 nautical miles of the donor hospital but outside of Zone B and the donor hospital's DSA.

5th: Zone D. Zone D includes all transplant hospitals that are within 2,500 nautical miles of the donor hospital but outside of Zone C.

6th: Zone E. Zone E includes all transplant hospitals that are more than 2,500 nautical miles from the donor hospital.

The local geographic ranking requires lungs to first be offered to candidates within the local DSA of the donor hospital irrespective of other candidates that may be a logistically reasonable distance away from the location of that donor hospital. There are 58 DSAs within the United States; New York State has 5 DSAs. The borders for each DSA are drawn arbitrarily, and are not based on geographic distance or the necessities fo medical logistics.

Medical Ranking: Within each geographic ranking, candidates are medically ranked by LAS and medical compatibility as follows:

1st: At least 12 years old, blood type identical to the donor.

2nd: At least 12 years old, blood type compatible with the donor.

3rd: Priority 1 and one of the following:

- Less than 12 years old and blood type identical to the donor
- Less than 1 year old and blood type compatible with the donor
- Less than 1 year old and eligible for intended blood group incompatible offers

4th: Priority 1 and one of the following:

- At least 1 year old and blood type compatible with the donor
- At least 1 year old and eligible for intended blood group incompatible offers

5th: Priority 2, blood type identical to the donor.

6th: Priority 2, blood type compatible with the donor.

Application of the Ranking System: Policy 10.4.C's inclusion of a first-tier geographic ranking that limits the availability of lungs to candidates within the donor's DSA results in an illogical, inequitable, and medically unsound allocation of donor lungs.

Under the current system, if a lung is accepted for a candidate within the local DSA, it is never offered to a candidate in the broader reach of the organ even if that non-local DSA candidate has a greater medical need, i.e., a higher LAS. Moreover, because of the arbitrary boundaries of DSAs, an available lung may not even be offered to the candidate closest to the donor hospital even if that candidate has a higher LAS score. Instead of following such a patently illogical allocation priority rule, UNOS should make available to a candidate with Miriam's recognized level of transplant need all medically compatible lungs that are donated within a logistically reasonable radius of her transplant hospital.

Simply put, OPTN Policy 10 is discriminatory and violates the legislatively mandated requirement that organ allocation be "based on sound medical judgment" and "not be based on the candidate's place of residence or place of listing." 42 C.F.R. §121.8(a).

4. OPTN's Policy 10 Is Recognized within the Medical Community as Being Discriminatory

The requirement that lungs be allocated within the local DSA before being offered more broadly has been recognized within the medical community as being flawed.

The Annals of Thoracic Surgery: This study concludes that "the locally based lung allocation system results in a high frequency of events whereby an organ is allocated to a lower-priority candidate while an appropriately matched higher priority candidate exists regionally. This may result unnecessarily in the death of higher priority candidates, thus diminishing waiting list outcomes and the net benefit of transplantation." Russo MJ, Meltzer D, Merlo A, Johnson E, Shariati NM, Sonett JR, Gibbons R., *Local allocation of lung donors results in transplanting lungs in lower priority transplant recipients*, Ann. Thorac. Surg. 2013; 95:1231-5 (Exhibit B).

Clinical Transplantation: Finding that "within the locally based lung allocation system, close to half of donor lungs go to patients with an LAS <50 and, in instances of broader geographical sharing, that proportion decreases." Iribarne A, Meltzer DO, Chauhan D, Sonett JR, Gibbons RD, Vigneswaran W, Russo MJ, *Distribution of donor lungs in the United States: a case for broader geographic sharing*, Clin. Transplant. 2016 Jun; 30(6):688-93 (Exhibit C).

See also Egan TM, *Ethical issues in thoracic organ distribution for transplant. Am J Transplant*. 2003 Apr; 3(4):366-72.

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Conclusion

HHS, OPTN, and Miriam all have a common goal – to make donor lungs available to those who need them the most based on medical criteria. All we request is that this goal be appropriately reflected in OPTN Policy 10 and that it be done in a timely manner so that it is not too late for Miriam. Miriam is not asking for anything more than she is entitled to under NOTA. It cannot possibly be that the system is so rigid that despite the compelling facts set forth in this letter Miriam must die rather than get a fair chance to receive a donated lung. Discretion and power rests with the Secretary to direct the OPTN for exactly this purpose – to avoid inequality and injustice. All we ask is that you set aside these flaws in OPTN Policy 10 until the OPTN can devise a better system after proper notice and comment to the public.

I hope that you will exercise your discretion in this matter as requested. In any event, I would appreciate it if you would ask the Department's counsel to call me so that we may make arrangements for delivery of any further papers or materials related to this matter as well as coordinate on any judicial intervention should that be necessary.

Yours truly,

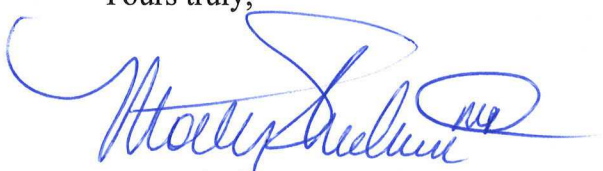

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EXHIBIT A

Policy 10: Allocation of Lungs

10.1 Priorities and Score Assignments for Lung Candidates

Lung candidates:

- Less than 12 years old are assigned a priority for lung allocation that is based on medical urgency.
- At least 12 years old use a Lung Allocation Score (LAS) to determine lung allocation, as well as geography and blood type.

10.1.A Candidates Less than 12 Years Old - Priority 1

A lung candidate less than 12 years old may be assigned priority 1 if at least *one* of the following requirements is met:

1. Candidate has respiratory failure, evidenced by at least *one* of the following:
   - Requires continuous mechanical ventilation
   - Requires supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% in order to maintain oxygen saturation levels greater than 90%
   - Has an arterial or capillary PCO_2 greater than 50 mm Hg
   - Has a venous PCO_2 greater than 56 mm Hg

2. Pulmonary hypertension, evidenced by at least *one* of the following:
   - Has pulmonary vein stenosis involving 3 or more vessels
   - Exhibits *any* of the following, in spite of medical therapy:
     - Cardiac index less than 2 L/min/M^2
     - Syncope
     - Hemoptysis
     - Suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate

The OPTN Contractor will maintain examples of accepted medical therapy for pulmonary hypertension. Transplant programs must indicate which of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant program must submit an exception request to the lung review board (LRB).

10.1.B Candidates Less than 12 Years Old - Priority 2

If a lung candidate less than 12 years old does not meet any of the above criteria to qualify for priority level 1, then the candidate is priority 2.

10.1.C Priority and Clinical Data Update Schedule for Candidates Less than 12 Years Old

A transplant program may update the reported clinical data to justify a candidate's priority at any time. When a candidate meets the requirements for priority 1 the candidate will remain at priority 1 for six months from the date first registered as priority 1 on the lung transplant waiting list.

To remain as priority 1, the transplant program must then update the required clinical data, except data that requires a heart catheterization, every six months following the first six months as a priority 1 candidate. The updates must occur in each six month period following the initial six months at priority 1 to remain at priority 1. The transplant program may determine the frequency of performing the heart catheterization.

If the data used to justify the priority 1 criteria are more than 6 months old at the 6-month anniversary date, other than data requiring a heart catheterization, the candidate will automatically be assigned priority 2.

Lung candidates registered on the waiting list at inactive status are subject to these same requirements for updating clinical data.

10.1.D Candidates at Least 12 Years Old - LAS

Candidates who are at least 12 years old or who have an approved adolescent classification exception receive offers for deceased donor lungs based on their calculated LAS. Candidates with a higher LAS receive higher waiting list priority within geography and blood type classifications.

10.1.E LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old

When registering a candidate who is at least 12 years old for a lung transplant, or when registering a candidate with an approved adolescent classification exception according to *Policy 10.2.B: Lung Candidates with Exceptional Cases*, transplant programs must report to the OPTN Contractor clinical data corresponding with to the covariates shown in *Table 10-3: Waiting List Mortality Calculation: Covariates and Their Coefficients* and *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.

The data reported at the time of the candidate's registration on the lung transplant waiting list must be six months old or less from the date of the candidate's registration date. The transplant program must maintain source documentation for all laboratory values reported in the candidate's medical chart.

Except as noted in *Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher*, transplant programs must report to the OPTN Contractor LAS covariate clinical data for every covariate in *Table 10-3* and *Table 10-4* for each candidate at least once in every six month period after the date of the candidate's initial registration or the LRB's approval of an adolescent classification exception. The first six-month period begins six months from the date of the candidate's initial registration, or, in the case of adolescent classification exceptions, six months from the date of LRB approval, with a new six-month period occurring every six months thereafter.

A covariate's value expires if the covariate's test date is six-months older than the most recent six-month anniversary date. The LAS system considers actual values and approved estimated values for pulmonary pressures to be valid until the transplant program updates them with new actual values or new approved estimated values as described in Policy *10.2.B.iii: Estimated Values Approved by the LRB*.

Transplant programs may report a medically reasonable estimated value if a test needed to obtain an actual value for a variable covariate cannot be performed due to the candidate's medical condition. Before entering estimated values, programs must receive approval from the LRB, which will determine whether the estimated values are appropriate according to *Policy 10.2.B.iii: Estimated Values Approved by the LRB.* Approved estimated values remain valid until an updated actual value is reported for the covariate, or until the transplant program reports a new, approved estimated value.

LAS covariate data obtained by heart catheterization does not need to be reported to the OPTN Contractor every six months. For LAS covariate data that requires a heart catheterization, the transplant program may determine the frequency of updating the data. However, if a transplant program performs a heart catheterization test on the candidate during the six month interval, then it must report the data to the OPTN Contractor.

If values for certain covariates are missing, expired, or below the threshold as defined by *Table 10-1*, then the LAS calculation will substitute normal or least beneficial values to calculate the candidate's LAS. A normal value is one that a healthy individual is likely to exhibit. A least beneficial value is one that will calculate the lowest LAS for a candidate. *Table 10-1* lists the normal and least beneficial values that will be substituted.

Table 10-1: Values Substituted for Missing or Expired Actual Values in Calculating the LAS

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
Bilirubin	Missing, expired, or less than 0.7 mg/dL	0.7 mg/dL
Body mass index (BMI)	Missing or expired	100 kg/m^2
Cardiac index	Missing	3.0 $L/min/m^2$
Central venous pressure (CVP)	Missing or less than 5 mm Hg	5 mm Hg
Continuous mechanical ventilation	Missing or expired	No mechanical ventilation in the waiting list model Continuous mechanical ventilation while hospitalized in the post-transplant survival measure
Creatinine: serum	Missing or expired	0.1 mg/dL in the waiting list model 40 mg/dL in the post-transplant survival measure for candidates at least 18 years old 0 mg/dL in the post-transplant survival measure for candidates less than 18 years old
Diabetes	Missing or expired	No diabetes
Forced vital capacity (FVC)	Missing or expired	150% for Diagnosis Group D

If this covariate's value:	Is:	Then the LAS calculation will use this substituted value:
Functional status	Missing or expired	No assistance needed in the waiting list model Some or total assistance needed in the post-transplant survival measure
Oxygen needed at rest	Missing or expired	No supplemental oxygen needed in the waiting list model 26.33 L/min in the post-transplant survival measure
PCO_2	Missing, expired, or less than 40 mm Hg	40 mm Hg
Pulmonary artery (PA) systolic pressure	Missing or less than 20 mm Hg	20 mm Hg
Six-minute-walk distance	Missing or expired	4,000 feet in the waiting list urgency measure 0 feet in the post-transplant survival measure

10.1.F The LAS Calculation

The LAS calculation uses *all* of the following measures:

- Waiting List Urgency Measure, which is the expected number of days a candidate will live without a transplant during an additional year on the waiting list.
- Post-transplant Survival Measure, which is the expected number of days a candidate will live during the first year post-transplant.
- Transplant Benefit Measure, which is the difference between the Post-transplant Survival Measure and the Waiting List Urgency Measure.
- Raw Allocation Score, which is the difference between Transplant Benefit Measure and Waiting List Urgency Measure.

To determine a candidate's LAS, the Raw Allocation Score is normalized to a continuous scale of zero to 100.

The equation for the LAS calculation is:

$$LAS = \frac{100 * [PTAUC - 2 * WLAUC + 730]}{1095}$$

Table 10-2: LAS Calculation Values

Where…	Includes…
$PTAUC = \sum_{k=0}^{364} S_{TX}(k)$	PTAUC = the area under the post-transplant survival probability curve during the first post-transplant year. β_I = the coefficient for characteristic i from the waiting list measure, according to *Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients.*
$S_{TX}(t) = S_{TX,0}(t)^{e^{\alpha_1 Y_1 + \alpha_2 Y_2 + \ldots + \alpha_q Y_q}}$	$S_{TX}(t)$ = the expected post-transplant survival probability at time t for an individual candidate. Y_i = the value of the j^{th} characteristic for an individual candidate α_j = the coefficient for characteristic j from the post-transplant survival measure, according to *Table 10-4: Post-Transplant Survival Calculation, Covariates, and Their Coefficients*.
$WLAUC = \sum_{k=0}^{364} S_{WL}(k)$	WLAUC = the area under the waiting list survival probability curve during the next year.
$S_{WL}(t) = S_{WL,0}(t)^{e^{\beta_1 X_1 + \beta_2 X_2 + \ldots + \beta_p X_p}}$	$S_{WL,0}(t)$ = the baseline waiting list survival probability at time t, according to *Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability*. $S_{TX,0}(t)$ = the baseline post-transplant survival probability at time t, according to *Table 10-12: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability*. $S_{WL}(t)$ = the expected waiting list survival probability at time t for an individual candidate X_i = the value of the i^{th} characteristic for an individual candidate.

Table 10-3 provides the covariates and their coefficients for the waiting list mortality calculation. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 10-3: Waiting List Mortality Calculation: Covariates and their Coefficients

For this covariate:	The following coefficient is used in the LAS calculation:
1. Age (year)	0.0083990318885565*age
2. Bilirubin (mg/dL)	0.0431682188302477*(bilirubin – 1) if bilirubin is more than 1.0 mg/dL 0 when bilirubin is 1.0 mg/dL or less
3. Bilirubin increase of at least 50%	1.4144058906830200 for Diagnosis Group B 0 for Diagnosis Groups A, C, and D

For this covariate:	The following coefficient is used in the LAS calculation:
4. Body mass index (BMI) (kg/m^2)	0.1261444133358100*(20 – BMI) for BMI less than 20 kg/m^2 0 if BMI is at least 20 kg/m^2
5. Cardiac index prior to any exercise	0.5435368888028200 if the cardiac index is less than 2 L/min/m^2 0 if the cardiac index is at least 2 L/min/m^2
6. Central venous pressure (CVP) (mm Hg) at rest, prior to any exercise	0.0173841981251578*(CVP – 7) for CVP greater than 7 mm Hg (Diagnosis Group B only) 0 if less than or equal to 7 mm Hg for Diagnosis Group B 0 for candidates in Diagnosis Groups A, C, and D
7. Ventilation status if candidate is hospitalized	1.6771121096052300 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
8. Creatinine (serum) (mg/dL)	0.5034346761960600* creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
9. Diabetes	0.4680254026735700 if diabetic 0 if not diabetic
10. Diagnosis Group A	0
11. Diagnosis Group B	1.5774243292137200
12. Diagnosis Group C	1.2313926484343600
13. Diagnosis Group D	0.6259577164157700
14. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.6680518055684700
15. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	-0.6278657824830000
16. Detailed diagnosis: Lymphangioleiomyomatosis (Diagnosis Group A only)	-0.3162937838984600
17. Detailed Diagnosis: Obliterative bronchiolitis (not-retransplant) (Diagnosis Group D only)	0.4453284411081100
18. Detailed Diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.2091170018125500

For this covariate:	The following coefficient is used in the LAS calculation:
19. Detailed Diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.4577749354638600
20. Detailed Diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	0.9330846239906700
21. Forced vital capacity (FVC)	0.1829476350587400*(80 – FVC)/10 if FVC is less than 80% for Diagnosis Group D 0 if FVC is greater than or equal to 80% for Diagnosis Group D 0 for candidates in Diagnosis Groups A, B, and C
22. Functional Status	-0.4471034284458400 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
23. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0213187586203456*O_2 for Diagnosis Group B 0.1188479817592500*O_2 for Diagnosis Groups A, C, and D
24. PCO_2 (mm Hg): current	0.1104609835819100*PCO_2/10 if PCO_2 is at least 40 mm Hg
25. PCO_2 increase of at least 15%	0.2331149280428300 if PCO_2 increase is at least 15% 0 if PCO_2 increase is less than 15%
26. Pulmonary artery (PA) systolic pressure (10 mm Hg) at rest, prior to any exercise	0.4155116686114300*(PA systolic – 40)/10 for Diagnosis Group A if the PA systolic pressure is greater than 40 mm Hg 0 for Diagnosis Group A if the PA systolic pressure is 40 mm Hg or less 0.0462410402627318*PA systolic/10 for Diagnosis Groups B, C, and D
27. Six-minute-walk distance (feet) obtained while the candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	-0.0844896372724000*Six-minute-walk distance/100

Table 10-4 lists the covariates and corresponding coefficients in the waiting list and post-transplant survival measures. See *Policy 10.1.F.i: Lung Disease Diagnosis Groups* for specific information on each diagnosis group.

Table 10-4: Post-Transplant Survival Calculation: Covariates and Their Coefficients

For this variable:	The following is used in the LAS calculation:
1. Age (years)	0.0246579831271869*(age–45) if candidate is greater than 45 years old 0 if candidate is 45 years old or younger
2. Creatinine (serum) at transplant (mg/dL)	0.0895569900508900*creatinine if candidate is at least 18 years old 0 if candidate is less than 18 years old
3. Creatinine increase of at least 150%	0.7708616024698100 if increase in creatinine is at least 150%, and the higher value determining this increase is at least 1 mg/dL 0 if increase in creatinine of 150% if the higher value determining this increase is less than 1 mg/dL 0 if increase in creatinine less than 150%
4. Cardiac index (L/min/m^2) at rest, prior to any exercise	0.3499381679822400 if less than 2 L/min/m^2 0 if at least 2 L/min/m^2
5. Ventilation status if candidate is hospitalized	0.6094478988424900 if continuous mechanical ventilation needed 0 if no continuous mechanical ventilation needed
6. Diagnosis Group A	0
7. Diagnosis Group B	0.6115547319209300
8. Diagnosis Group C	0.3627014422464200
9. Diagnosis Group D	0.4641392063023200
10. Detailed diagnosis: Bronchiectasis (Diagnosis Group A only)	0.1889100379099400
11. Detailed diagnosis: Eisenmenger's syndrome (Diagnosis Group B only)	0.9146727886744700
12. Detailed diagnosis: Lymphangioleiomyomatosis (Diagnosis Group A only)	-1.5194416206749400
13. Detailed diagnosis: Obliterative bronchiolitis (not-retransplant, Diagnosis Group D only)	-1.2050508750702600
14. Detailed diagnosis: Pulmonary fibrosis, not idiopathic (Diagnosis Group D only)	-0.0723596761367600

For this variable:	The following is used in the LAS calculation:
15. Detailed diagnosis: Sarcoidosis with PA mean pressure greater than 30 mm Hg (Diagnosis Group D only)	-0.0437880049066331
16. Detailed diagnosis: Sarcoidosis with PA mean pressure of 30 mm Hg or less (Diagnosis Group A only)	-0.1389363636019300
17. Oxygen needed to maintain adequate oxygen saturation (88% or greater) at rest (L/min)	0.0747978926517300*O_2 for Diagnosis Group A 0.0164276945879309*O_2 for Diagnosis Groups B, C, and D
18. Functional Status	-0.1900086366785100 if no assistance needed with activities of daily living 0 if some or total assistance needed with activities of daily living
19. Six-minute-walk-distance (feet) obtained while candidate is receiving supplemental oxygen required to maintain an oxygen saturation of 88% or greater at rest. Increase in supplemental oxygen during this test is at the discretion of the center performing the test.	0.0004594953809594*(1200-Six-minute-walk distance) 0 if six-minute-distance-walked is at least 1,200 feet

See *Policy 10.5: Probability Data Used in the LAS Calculation* for *Tables 10-11* and *10-12* that provide data used in the LAS calculation.

10.1.F.i Lung Disease Diagnosis Groups

The LAS calculation uses diagnosis Groups A, B, C, and D as listed below.

Group A

A candidate is in Group A if the candidate has *any* of the following diagnoses:

- Allergic bronchopulmonary aspergillosis
- Alpha-1 antitrypsin deficiency
- Bronchiectasis
- Bronchopulmonary dysplasia
- Chronic obstructive pulmonary disease/emphysema
- Ehlers-Danlos syndrome
- Granulomatous lung disease
- Inhalation burns/trauma
- Kartagener's syndrome
- Lymphangioleiomyomatosis
- Obstructive lung disease
- Primary ciliary dyskinesia;
- Sarcoidosis with mean pulmonary artery pressure of 30 mm Hg or less
- Tuberous sclerosis
- Wegener's granuloma – bronchiectasis

Group B

A candidate is in Group B if the candidate has any of the following diagnoses:

- Congenital malformation
- CREST – pulmonary hypertension
- Eisenmenger's syndrome: atrial septal defect (ASD)
- Eisenmenger's syndrome: multi-congenital anomalies
- Eisenmenger's syndrome: other specify
- Eisenmenger's syndrome: patent ductus arteriosus (PDA)
- Eisenmenger's syndrome: ventricular septal defect (VSD)
- Portopulmonary hypertension
- Primary pulmonary hypertension/pulmonary arterial hypertension
- Pulmonary capillary hemangiomatosis
- Pulmonary telangiectasia – pulmonary hypertension
- Pulmonary thromboembolic disease
- Pulmonary vascular disease
- Pulmonary veno-occlusive disease
- Pulmonic stenosis
- Right hypoplastic lung
- Scleroderma – pulmonary hypertension
- Secondary pulmonary hypertension
- Thromboembolic pulmonary hypertension

Group C

A candidate is in Group C if the candidate has *any* of the following diagnoses:

- Common variable immune deficiency
- Cystic fibrosis
- Fibrocavitary lung disease
- Hypogammaglobulinemia
- Schwachman-Diamond syndrome

Group D

A candidate is in Group D if the candidate has *any* of the following diagnoses:

- ABCA3 transporter mutation
- Alveolar proteinosis
- Amyloidosis
- Acute respiratory distress syndrome or pneumonia
- Bronchioloalveolar carcinoma (BAC)
- Carcinoid tumorlets
- Chronic pneumonitis of infancy
- Constrictive bronchiolitis
- CREST – Restrictive
- Eosinophilic granuloma
- Fibrosing Mediastinitis
- Graft versus host disease (GVHD)
- Hermansky Pudlak syndrome
- Hypersensitivity pneumonitis

- Idiopathic interstitial pneumonia, with at least one or more of the following disease entities:
  - Acute interstitial pneumonia
  - Cryptogenic organizing pneumonia/Bronchiolitis obliterans with organizing pneumonia (BOOP)
  - Desquamative interstitial pneumonia
  - Idiopathic pulmonary fibrosis (IPF)
  - Nonspecific interstitial pneumonia
  - Lymphocytic interstitial pneumonia (LIP)
  - Respiratory bronchiolitis-associated interstitial lung disease
- Idiopathic pulmonary hemosiderosis
- Lung retransplant or graft failure: acute rejection
- Lung retransplant or graft failure: non-specific
- Lung retransplant or graft failure: obliterative bronchiolitis-obstructive
- Lung retransplant or graft failure: obliterative bronchiolitis-restrictive
- Lung retransplant or graft failure: obstructive
- Lung retransplant or graft failure: other specify
- Lung retransplant or graft failure: primary graft failure
- Lung retransplant or graft failure: restrictive
- Lupus
- Mixed connective tissue disease
- Obliterative bronchiolitis: non-retransplant
- Occupational lung disease: other specify
- Paraneoplastic pemphigus associated Castleman's disease
- Polymyositis
- Pulmonary fibrosis: other specify cause
- Pulmonary hyalinizing granuloma
- Pulmonary lymphangiectasia (PL)
- Pulmonary telangiectasia – restrictive
- Rheumatoid disease
- Sarcoidosis with mean pulmonary artery pressure higher than 30 mm Hg
- Scleroderma – restrictive
- Secondary pulmonary fibrosis: (specify cause)
- Silicosis
- Sjogren's syndrome
- Surfactant protein B mutation
- Surfactant protein C mutation
- Teratoma
- Wegener's granuloma – restrictive

10.1.F.ii PCO2 in the LAS

The LAS calculation uses two measures of PCO_2:

1. Current PCO_2
2. PCO_2 Threshold Change

Current PCO_2

Current PCO_2 is the PCO_2 value reported to the OPTN Contractor with the most recent test date and time. A program may report a PCO_2 value from an arterial,

venous, or capillary blood gas test. All blood gas values will be converted to an arterial value as follows:

- A capillary value will equal an arterial value.
- A venous value minus 6 mmHg equals an arterial value.

PCO_2 Threshold Change

There are two PCO_2 threshold change calculations:

- The PCO_2 Threshold Change Calculation
- The Threshold Change Maintenance Calculation

The PCO_2 Threshold Change Calculation

An increase in PCO_2 that is at least 15% will impact a candidate's LAS. If a value is less than 40 mmHg, the system will substitute the normal clinical value of 40 mmHg before calculating change. The PCO_2 threshold change calculation uses the highest and lowest values of PCO_2 as follows:

- The test date and time of the lowest value reported to the OPTN Contractor used in the PCO_2 threshold change calculation must be earlier than the test date and time of the highest value used in the PCO_2 threshold change calculation.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The PCO_2 threshold change calculation can use an expired lowest value, but cannot use an expired highest value.

If a current PCO_2 value expires according *to Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old,* the candidate's LAS will lose the impact from the PCO_2 threshold change calculation. The equation for the PCO_2 threshold change calculation is:

$$\frac{\text{Highest } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The Threshold Change Maintenance Calculation

When a 15% or greater PCO_2 threshold change calculation impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the PCO_2 increase, the candidate's current PCO_2 value must be at least 15% higher than the lowest value used in the PCO_2 threshold change calculation. The equation for this threshold change maintenance calculation is:

$$\frac{\text{Current } PCO_2 - \text{Lowest } PCO_2}{\text{Lowest } PCO_2}$$

The threshold change maintenance calculation occurs either when the current PCO_2 value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or a new current PCO_2 value is entered. For this calculation, the lowest and highest values that were used in the PCO_2 threshold change calculation can be expired. The current PCO_2 value can be the highest one that was used in the PCO_2 threshold change calculation. If a current PCO_2 value expires, the candidate's LAS will no longer be affected by the PCO_2 threshold change.

If a transplant hospital reports a new current PCO_2 value for a candidate who has lost the impact from the PCO_2 threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current PCO_2 value is at least 15% higher than the lowest value used in the PCO_2 threshold change calculation, the candidate's LAS will again be affected by the PCO_2 threshold change calculation.

Normal PCO_2 Value

The normal clinical PCO_2 value is 40mmHg. If a current PCO_2 value is below 40 mmHg, or if the current PCO_2 value is missing or expired, the LAS calculation will use the normal clinical PCO_2 value.

10.1.F.iii Bilirubin in the LAS

The LAS calculation uses two measures of total bilirubin:

- Current bilirubin (for all candidates)
- Bilirubin Threshold Change (for diagnosis Group B only)

Current Bilirubin

Current bilirubin is the total bilirubin value with the most recent test date and time reported to the OPTN Contractor. A current bilirubin value greater than 1.0 mg/dL will impact candidate's LAS.

Bilirubin Threshold Change (Diagnosis Group B Only)

There are two Bilirubin threshold change calculations:

- Bilirubin Threshold Change Calculation
- Threshold Change Maintenance Calculation

Bilirubin Threshold Change Calculation

For candidates in diagnosis Group B, an increase-in-bilirubin that is at least 50% impacts the candidate's LAS. The bilirubin threshold change calculation uses the highest and lowest values of bilirubin as follows:

- The test date and time of the lowest bilirubin value reported to the OPTN Contractor used in the bilirubin threshold change calculation must be earlier than the test date and time of the highest bilirubin value used in the bilirubin threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The bilirubin threshold calculation can use an expired lowest value, but cannot use an expired highest value.
- If a value is less than 0.7 mg/dL, the bilirubin threshold change calculation will use the normal clinical value of 0.7 mg/dL.

The equation for this bilirubin threshold change calculation is:

$$\frac{\text{Highest Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

Threshold Change Maintenance Calculation

When a 50% or greater increase in bilirubin impacts a candidate's LAS, the LAS threshold change maintenance calculation assesses whether to maintain that impact.

To maintain the impact of the bilirubin increase, the candidate's current bilirubin value must be at least 1.0 mg/dL and at least 50% higher than the lowest value used in the bilirubin threshold change calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Bilirubin-Lowest Bilirubin}}{\text{Lowest Bilirubin}}$$

The threshold change maintenance calculation occurs either when the current bilirubin value expires, according to *Policy 10.1.E: LAS Values and Clinical Data Update Schedule for Candidates at Least 12 Years Old*, or a new current bilirubin value is entered. For this calculation, the lowest and highest values that were used in the bilirubin threshold change calculation can be expired. The current bilirubin value can be the highest one that was used in the bilirubin threshold change calculation. If a current bilirubin value expires, the candidate's LAS will no longer be affected by the bilirubin threshold change.

If a transplant hospital reports a new current bilirubin value for a candidate who has lost the impact from the bilirubin threshold change calculation, the LAS will perform the threshold change maintenance calculation. If the new current bilirubin value is at least 50% higher than the lowest value used in the bilirubin threshold change calculation, the candidate's LAS will again be affected by the bilirubin threshold change calculation.

Normal Bilirubin Value

The normal clinical current bilirubin value is 0.7 mg/dL. If a current bilirubin value is below 0.7 mg/dL, or if the current bilirubin value is missing or expired, the LAS calculation will use the normal clinical current bilirubin value.

10.1.F.iv Creatinine in the LAS

The LAS calculation uses two measures of creatinine:

1. Current creatinine (only for candidates who are at least 18 years old)
2. Creatinine Threshold Change (for all candidates)

Current Creatinine

Current creatinine is the serum creatinine value with the most recent test date and time reported to the OPTN Contractor for candidates who are at least 18 years old.

Creatinine Threshold Change Calculations

There are two creatinine threshold change calculations:

1. Creatinine Threshold Change Calculation
2. Threshold Change Maintenance Calculation

The Creatinine Threshold Change Calculation

An increase in creatinine that is at least 150% will impact a candidate's LAS. The creatinine threshold change calculation uses the highest and lowest values of creatinine as follows:

- The test date and time of the lowest creatinine value reported to the OPTN Contractor used in the creatinine threshold change calculation must be earlier

than the test date and time of the highest creatinine value used in the creatinine threshold change calculation.
- The highest value must be at least 1.0 mg/dL.
- Test dates of these highest and lowest values cannot be more than six months apart.
- The creatinine threshold change calculation can use an expired lowest value, but cannot use an expired highest value.

The equation for this creatinine threshold change calculation is:

$$\frac{\text{Highest Creatinine-Lowest Creatinine}}{\text{Lowest Creatinine}}$$

The Threshold Change Maintenance Calculation

When a creatinine threshold change calculation impacts a candidate's LAS, the threshold change maintenance calculation assesses whether to maintain that impact. To maintain the impact of the increase in creatinine, the candidate's current creatinine value must be at least 1.0 mg/dL and at least 150% higher than the lowest value used in the creatinine threshold change calculation. The equation for the threshold change maintenance calculation is:

$$\frac{\text{Current Creatinine-Lowest Creatinine}}{\text{Lowest Creatinine}}$$

If the current creatinine value expires or a new creatinine value is entered, then the threshold change maintenance calculation will occur.

10.1.G Reporting Additional Data for Candidates with an LAS of 50 or Higher

Within 14 days of the date a candidate's LAS becomes 50 or higher, the candidate's transplant program must assess and report to the OPTN Contractor the following variables:

1. Assisted ventilation
2. Supplemental oxygen
3. Current PCO_2

While the candidate's LAS remains 50 or higher, the transplant program must continue to assess and report assisted ventilation and supplemental oxygen data every 14 days. The transplant program is only required to report updated PCO_2 data if the assessment was performed during the previous 14 day interval.

The transplant program must maintain documentation of each assessment in the candidate's medical chart.

10.2 Priority and Score Exceptions

10.2.A Allocation Exception for Sensitized Patients

Lungs may be allocated to sensitized candidates within a DSA out of the sequence required by the match run if:

1. The candidate's transplant surgeon or physician determines that the candidate's antibodies would react adversely to certain human leukocyte antigens (HLA) antigens.

2. All lung transplant programs and the OPO within the DSA agree to allocate the lung from a compatible deceased donor to the sensitized candidate because the results of a crossmatch between the blood serum of that the candidate and cells of the lung donor are negative.
3. The candidate's transplant program, all lung transplant programs, and the OPO within a DSA agree upon the level of sensitization at which a candidate qualifies for the sensitization exception.

Sensitization alone does not qualify a candidate to qualify for an exception as described in *Policy 10.2.B*: *Lung Candidates with Exceptional Cases* below.

10.2.B Lung Candidates with Exceptional Cases

The Thoracic Organ Transplantation Committee establishes guidelines for special case review by the LRB.

If a candidate's transplant program believes that a candidate's current priority or LAS does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may request approval of a specific priority or LAS by the LRB. The transplant program can also ask the LRB to approve specific estimated values or diagnoses.

For lung candidates less than 12 years old, transplant programs may request classification as an adolescent candidate for the purposes of *Policy 10.4.C: Allocation of Lungs from Deceased Donors at Least 18 Years Old*, and *Policy 10.4.D: Allocation of Lungs from Deceased Donors 12 to Less Than 18 Years Old*. Candidates receiving this exception will also maintain their pediatric classification for the purposes of *Policy 10.4.E: Allocation of Lungs from Deceased Donors Less than 12 Years Old*.

10.2.B.i LRB Review Process

Requests for approval of estimated values, diagnoses, specific LAS, or adolescent classification exceptions require prospective review by the LRB. The transplant hospital must submit requests for LRB review to the OPTN Contractor, and accompany each request for special review with a supporting narrative. The LRB will have seven days to reach a decision regarding the request, starting from the date that the OPTN Contractor sends the request to the LRB.

If the LRB denies a request upon initial review, then the transplant program may choose to appeal the decision and request reconsideration by the LRB. The transplant program has seven days from the date of the initial denial of the initial request to appeal. The LRB has seven days to reach a decision on the appeal, starting from the date that the OPTN Contractor sends the appealed request to the LRB. If the LRB does not complete its review of an initial request or appeal within seven days of receiving it, then the candidate will not receive the requested LAS, diagnosis, estimated value, or adolescent classification, and the OPTN Contractor will send the request or appeal to the Thoracic Organ Transplantation Committee for further review.

Requests to register a candidate less than 12 years old as priority 1 require retrospective LRB review by the LRB.

10.2.B.ii LRB Decision Overrides

If the LRB denies a transplant hospital's initial request or appeal for an estimated value, adolescent classification, or specific LAS on appeal, the transplant hospital has the option to override the decision of the LRB. If the transplant hospital elects to override the decision of the LRB, then the OPTN Contractor will send the request or

appeal to the Thoracic Organ Transplantation Committee for review. This review by the Thoracic Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee (MPSC). If the MPSC agrees with the Thoracic Organ Transplantation Committee's decision, a member who has registered a candidate with an unapproved estimated value, adolescent classification, or LAS will be subject to action according to *Appendix L: Reviews, Actions, and Due Process* of the *OPTN Bylaws*.

10.2.B.iii Estimated Values Approved by the LRB

Approved estimated values approved by the LRB or Thoracic Committee are valid until an actual value is reported to the OPTN Contractor or a new estimated value is reported to the OPTN Contractor.

10.2.B.iv LAS Diagnoses Approved by the LRB

A diagnosis that has been approved by the LRB or the Thoracic Organ Transplantation Committee is valid indefinitely, or until an adjustment is requested and, if necessary, approved by the LRB.

10.2.B.v LAS Approved by the LRB

An LAS approved by the LRB or the Thoracic Committee will remain valid for six months from the date the candidate's LAS is updated, (or from the candidate's twelfth birthday, whichever occurs later). If the candidate is still on the waiting list six months after the date the LAS is updated, then the candidate's LAS will be computed as described in Policy *10.1: Priorities and Score Assignments for Lung Candidates* unless a new LAS or priority request is submitted to the OPTN Contractor.

10.3 Waiting Time

Waiting time for lung candidates begins when the candidate is registered on the waiting list. Candidates at least 12 years old awaiting a lung transplant on the waiting list at inactive status will not accrue any waiting time while at inactive status. Lung candidates less than 12 years old accrue waiting time when registered at inactive status.

When waiting time is used for lung allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same priority or LAS.

10.3.A Lung Candidates at Least 12 Years Old

If multiple candidates have identical computed LASs greater than zero, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time of each candidate's most recent data used in the calculation of the LAS reported to the OPTN Contractor.

If multiple candidates have identical assigned LASs due to an exceptional case request as defined by *Policy 10.2.B*, and have identical priority for a lung offer considering all other allocation factors, then priority among those candidates will be determined by the earliest date and time that each candidate's most recent LRB approval of that LAS was reported to the OPTN Contractor.

10.3.B Lung Candidates Less than 12 Years Old

Allocation ranking for a priority 1 lung candidate is based on the candidate's most recent priority 1 waiting time, which only includes the candidate's current time as priority 1 and does not include any previous time spent as priority 1.

If there is ever a tie among priority 1 candidates within the same classification due to identical priority 1 waiting times, then the lung will be allocated to the priority 1 candidate with the most total waiting time. Total waiting time includes time spent waiting as priority 1, priority 2, and at inactive status. Allocation ranking will also consider this total waiting time.

Among priority 2 candidates, allocation ranking considers total waiting time for receiving deceased donor lung offers. Total waiting time includes the time a candidate spent waiting as priority 1, priority 2, and inactive. A priority 2 lung candidate's waiting time is the same as total waiting time.

10.4 Lung Allocation Classifications and Rankings

10.4.A Sorting Within Each Classification

Lung candidates at least 12 years old are sorted in the following order:

1. LAS (highest to lowest)
2. Total active waiting time (longest to shortest)
3. LAS variable update date and time (earliest to most recent approval)
4. LAS exception date (earliest to most recent approval)

Lung candidates less than 12 years old are sorted in the following order:

1. Pediatric priority waiting time (longest to shortest)
2. Total waiting time (longest to shortest)

10.4.B Allocation of Lungs by Blood Type

A deceased donor's blood type compatibility with a lung candidate is defined in *Table 10-5* below.

Table 10-5: Deceased Donor Blood Type Compatibility with a Lung Candidate

Deceased Donor's Blood Type	Candidate's Blood Type			
	O	A	B	AB
O	Identical	Compatible	Compatible	Compatible
A	Screened*	Identical	Screened*	Compatible
B	Screened*	Screened*	Identical	Compatible
AB	Screened*	Screened*	Screened*	Identical

*Screened from match run, unless eligible for intended blood group incompatible offers according to *Policy 10.4.B.i*.

10.4.B.i Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

Candidates will be eligible for intended blood group incompatible deceased donor lungs if they meet the requirements according to *Table 10-6* below.

Table 10-6: Eligibility for Intended Blood Group Incompatible Offers for Deceased Donor Lungs

If the candidate is:	And meets *all* of the following:
Less than one year old at the time of the match run	1. Is priority 1. 2. Has reported isohemagglutinin titer information for A or B blood type antigens to the OPTN Contractor within the last 30 days.
At least one year old at the time of the match run	1. Is registered prior to turning two years old. 2. Is priority 1. 3. Has reported to the OPTN Contractor isohemagglutinin titers less than or equal to 1:16 for A or B blood type antigens from a blood sample collected within the last 30 days. The candidate must not have received treatments that may have reduced isohemagglutinin titers to 1:16 or less within 30 days of when this blood sample was collected.

10.4.B.ii Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

If a laboratory provides more than one isohemagglutinin titer value for a tested blood sample, the transplant program must report the highest titer value to the OPTN Contractor.

Accurate isohemagglutinin titers must be reported for candidates eligible for an intended blood group incompatible lung, according to *Table 10-7* below, at *all* of the following times:

1. Upon initially reporting that a candidate is willing to accept an intended blood group incompatible lung.
2. Every 30 days after initially reporting that a candidate is willing to accept an intended blood group incompatible lung.

Table 10-7: Isohemagglutinin Titer Reporting Requirements for a Candidate Willing to Receive an Intended Blood Group Incompatible Lung

If the candidate's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:
A	Anti-B
B	Anti-A
O	Anti-A and Anti-B

Accurate isohemagglutinin titers must be reported for recipients of an intended blood group incompatible lung, according to *Table 10-8*, as follows:

1. At transplant, from a blood sample taken within 24 hours prior to transplant.

2. If graft loss occurs within one year after transplant from the most recent sample, if available.
3. If recipient death occurs within one year after transplant from the most recent blood sample, if available.

Table 10-8: Isohemagglutinin Titer Reporting Requirements for a Recipient of an Intended Blood Group Incompatible Lung

If the deceased donor's blood type is:	And the recipient's blood type is:	Then the transplant program must report the following isohemagglutinin titers to the OPTN Contractor:
A	B or O	Anti-A
B	A or O	Anti-B
AB	A	Anti-B
AB	B	Anti-A
AB	O	Anti-A and Anti-B

10.4.C Allocation of Lungs from Deceased Donors at Least 18 Years Old

Single and double lungs from deceased donors at least 18 years old are allocated according to *Table 10-9* below.

Table 10-9: Allocation of Lungs from Deceased Donors at Least 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA	At least 12 years old, blood type identical to the donor
2	OPO's DSA	At least 12 years old, blood type compatible with the donor
3	OPO's DSA	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
4	OPO's DSA	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
5	OPO's DSA	Priority 2, blood type identical to the donor
6	OPO's DSA	Priority 2, blood type compatible with the donor
7	Zone A	At least 12 years old, blood type identical to the donor
8	Zone A	At least 12 years old, blood type compatible with the donor
9	Zone A	Priority 1 and *one* of the following:

Classification	Candidates that are included within the:	And are:
		• Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
10	Zone A	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
11	Zone A	Priority 2, blood type identical to the donor
12	Zone A	Priority 2, blood type compatible with the donor
13	Zone B	At least 12 years old, blood type identical to the donor
14	Zone B	At least 12 years old, blood type compatible with the donor
15	Zone B	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
16	Zone B	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
17	Zone B	Priority 2, blood type identical to the donor
18	Zone B	Priority 2, blood type compatible with the donor
19	Zone C	At least 12 years old, blood type identical to the donor
20	Zone C	At least 12 years old, blood type compatible with the donor
21	Zone C	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
22	Zone C	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor

Classification	Candidates that are included within the:	And are:
		• At least 1 year old and eligible for intended blood group incompatible offers
23	Zone C	Priority 2, blood type identical to the donor
24	Zone C	Priority 2, blood type compatible with the donor
25	Zone D	At least 12 years old, blood type identical to the donor
26	Zone D	At least 12 years old, blood type compatible with the donor
27	Zone D	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
28	Zone D	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
29	Zone D	Priority 2, blood type identical to the donor
30	Zone D	Priority 2, blood type compatible with the donor
31	Zone E	At least 12 years old, blood type identical to the donor
32	Zone E	At least 12 years old, blood type compatible with the donor
33	Zone E	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
34	Zone E	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
35	Zone E	Priority 2, blood type identical to the donor
36	Zone E	Priority 2, blood type compatible with the donor

10.4.D Allocation of Lungs from Deceased Donors Less than 18 Years Old

Single and double lungs from deceased donors less than 18 years old are allocated according to *Table 10-10* below.

Table 10-10: Allocation of Lungs from Deceased Donors Less than 18 Years Old

Classification	Candidates that are included within the:	And are:
1	OPO's DSA, Zone A, or Zone B	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
2	OPO's DSA, Zone A, or Zone B	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
3	OPO's DSA, Zone A, or Zone B	Priority 2, blood type identical to the donor
4	OPO's DSA, Zone A, or Zone B	Priority 2, blood type compatible with the donor
5	OPO's DSA, Zone A, or Zone B	12 to less than 18 years old, blood type identical to the donor
6	OPO's DSA, Zone A, or Zone B	12 to less than 18 years old, blood type compatible with the donor
7	OPO's DSA	At least 18 years, blood type identical to the donor
8	OPO's DSA	At least 18 years, blood type compatible with the donor
9	Zone A	At least 18 years old, blood type identical to the donor
10	Zone A	At least 18 years old, blood type compatible with the donor
11	Zone B	At least 18 years old, blood type identical to the donor
12	Zone B	At least 18 years old, blood type compatible with the donor
13	Zone C	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
14	Zone C	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
15	Zone C	Priority 2, blood type identical to the donor
16	Zone C	Priority 2, blood type compatible with the donor
17	Zone C	12 to less than 18 years old, blood type identical to the donor
18	Zone C	12 to less than 18 years old, blood type compatible with the donor
19	Zone C	At least 18 years old, blood type identical to the donor
20	Zone C	At least 18 years old, blood type compatible with the donor
21	Zone D	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers
22	Zone D	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
23	Zone D	Priority 2, blood type identical to the donor
24	Zone D	Priority 2, blood type compatible with the donor
25	Zone D	12 to less than 18 years old, blood type identical to the donor
26	Zone D	12 to less than 18 years old, blood type compatible with the donor
27	Zone D	At least 18 years old, blood type identical to the donor
28	Zone D	At least 18 years old, blood type compatible with the donor
29	Zone E	Priority 1 and *one* of the following: • Less than 12 years old and blood type identical to the donor • Less than 1 year old and blood type compatible with the donor • Less than 1 year old and eligible for intended blood group incompatible offers

Classification	Candidates that are included within the:	And are:
30	Zone E	Priority 1 and *one* of the following: • At least 1 year old and blood type compatible with the donor • At least 1 year old and eligible for intended blood group incompatible offers
31	Zone E	Priority 2, blood type identical to the donor
32	Zone E	Priority 2, blood type compatible with the donor
33	Zone E	12 to less than 18 years old, blood type identical to the donor
34	Zone E	12 to less than 18 years old, blood type compatible with the donor
35	Zone E	At least 18 years old, blood type identical to the donor
36	Zone E	At least 18 years old, blood type compatible with the donor

10.5 Probability Data Used in the LAS Calculation

Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
0	1.0000000000	49	0.9966437334	98	0.9931596573	147	0.9905400510	196	0.9872991723
1	0.9999907157	50	0.9965433845	99	0.9930980163	148	0.9905400510	197	0.9872626749
2	0.9999254055	51	0.9965175429	100	0.9930607383	149	0.9905400510	198	0.9871552755
3	0.9998674170	52	0.9963972737	101	0.9930052489	150	0.9905400510	199	0.9871220338
4	0.9997455435	53	0.9963972737	102	0.9930052489	151	0.9905400510	200	0.9865302072
5	0.9995975343	54	0.9963631304	103	0.9929378277	152	0.9903840245	201	0.9865302072
6	0.9994989961	55	0.9963053385	104	0.9929378277	153	0.9903328361	202	0.9864801346
7	0.9993713802	56	0.9961914895	105	0.9928829296	154	0.9903328361	203	0.9859628001
8	0.9993046242	57	0.9961189511	106	0.9928829296	155	0.9903328361	204	0.9859256159
9	0.9992177050	58	0.9959421227	107	0.9928506946	156	0.9902446847	205	0.9859256159
10	0.9990851999	59	0.9959421227	108	0.9927619069	157	0.9902446847	206	0.9858198690
11	0.9989901794	60	0.9959092500	109	0.9927244496	158	0.9902446847	207	0.9858198690
12	0.9988873318	61	0.9959092500	110	0.9926433860	159	0.9901449203	208	0.9857415923
13	0.9988160788	62	0.9958731922	111	0.9926433860	160	0.9896887318	209	0.9857415923
14	0.9987295863	63	0.9958457969	112	0.9925624932	161	0.9896887318	210	0.9857415923
15	0.9986602768	64	0.9958457969	113	0.9920885646	162	0.9896520090	211	0.9857075131
16	0.9985875403	65	0.9956136053	114	0.9920640055	163	0.9895745634	212	0.9857075131
17	0.9984554393	66	0.9955529860	115	0.9920400127	164	0.9895745634	213	0.9855411680
18	0.9983616851	67	0.9955529860	116	0.9919966080	165	0.9889025189	214	0.9855411680
19	0.9982588046	68	0.9955529860	117	0.9919660469	166	0.9888730124	215	0.9855411680
20	0.9982200289	69	0.9955000986	118	0.9919399263	167	0.9888730124	216	0.9854501485
21	0.9980677506	70	0.9954789372	119	0.9919399263	168	0.9887838841	217	0.9854501485
22	0.9980357372	71	0.9953493820	120	0.9919399263	169	0.9887222824	218	0.9854501485
23	0.9979724590	72	0.9952934145	121	0.9915144847	170	0.9886945957	219	0.9853304718
24	0.9978684291	73	0.9951363273	122	0.9915144847	171	0.9886945957	220	0.9852652088
25	0.9977699910	74	0.9949654223	123	0.9915144847	172	0.9886945957	221	0.9852652088
26	0.9977420222	75	0.9948209678	124	0.9915144847	173	0.9886549235	222	0.9852652088
27	0.9976665328	76	0.9947736691	125	0.9914883902	174	0.9886549235	223	0.9852652088
28	0.9976255053	77	0.9947021905	126	0.9914618560	175	0.9886549235	224	0.9852652088
29	0.9975404117	78	0.9947021905	127	0.9913925084	176	0.9886246774	225	0.9846212073
30	0.9974725579	79	0.9946337898	128	0.9913069760	177	0.9885475245	226	0.9845486667
31	0.9973914097	80	0.9945649862	129	0.9913069760	178	0.9885475245	227	0.9845486667
32	0.9973268946	81	0.9945465023	130	0.9912697831	179	0.9885475245	228	0.9845486667
33	0.9972974521	82	0.9944645092	131	0.9912361687	180	0.9880619575	229	0.9845486667
34	0.9972743143	83	0.9944645092	132	0.9912361687	181	0.9880619575	230	0.9844886959
35	0.9972419197	84	0.9942969766	133	0.9910529687	182	0.9880619575	231	0.9844886959
36	0.9972419197	85	0.9942969766	134	0.9910121623	183	0.9880212199	232	0.9843962284
37	0.9971814314	86	0.9942969766	135	0.9910121623	184	0.9879335450	233	0.9843236173
38	0.9971367830	87	0.9942969766	136	0.9909776544	185	0.9878851712	234	0.9842799561
39	0.9971209292	88	0.9941805902	137	0.9909776544	186	0.9878851712	235	0.9840794709
40	0.9971209292	89	0.9940771789	138	0.9909776544	187	0.9878851712	236	0.9840794709
41	0.9970189115	90	0.9940345018	139	0.9909355857	188	0.9878851712	237	0.9840145629
42	0.9969461979	91	0.9940082090	140	0.9909011142	189	0.9878560942	238	0.9840145629
43	0.9969159237	92	0.9938663826	141	0.9909011142	190	0.9878560942	239	0.9840145629
44	0.9968488001	93	0.9938313146	142	0.9908111395	191	0.9878560942	240	0.9840145629
45	0.9968488001	94	0.9938070978	143	0.9907387924	192	0.9878560942	241	0.9838347625
46	0.9968199961	95	0.9937145919	144	0.9905945464	193	0.9878560942	242	0.9838347625
47	0.9967799694	96	0.9933077154	145	0.9905945464	194	0.9876077782	243	0.9837917116
48	0.9967313053	97	0.9932199214	146	0.9905400510	195	0.9873585581	244	0.9837534417

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Table 10-11: Baseline Waiting List Survival (SWL(t)) Probability Where t=Time in Days (Continued)

t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$	t	$S_{WL}(t)$
245	0.9837534417	**269**	0.9829597020	**293**	0.9818267812	**317**	0.9802178676	**341**	0.9785965606
246	0.9837534417	**270**	0.9829597020	**294**	0.9818267812	**318**	0.9801289145	**342**	0.9785965606
247	0.9836972199	**271**	0.9827972342	**295**	0.9815730256	**319**	0.9801289145	**343**	0.9783012252
248	0.9836363251	**272**	0.9827972342	**296**	0.9813194319	**320**	0.9800157994	**344**	0.9782502701
249	0.9836363251	**273**	0.9827972342	**297**	0.9807747475	**321**	0.9800157994	**345**	0.9782502701
250	0.9836363251	**274**	0.9827972342	**298**	0.9807747475	**322**	0.9800157994	**346**	0.9782502701
251	0.9836363251	**275**	0.9827004206	**299**	0.9805186284	**323**	0.9797725024	**347**	0.9781167565
252	0.9832432776	**276**	0.9826027019	**300**	0.9803970706	**324**	0.9797725024	**348**	0.9780370471
253	0.9832432776	**277**	0.9826027019	**301**	0.9803970706	**325**	0.9796706377	**349**	0.9780370471
254	0.9832432776	**278**	0.9825107450	**302**	0.9803970706	**326**	0.9796706377	**350**	0.9780370471
255	0.9830967678	**279**	0.9824570403	**303**	0.9803970706	**327**	0.9791639481	**351**	0.9780370471
256	0.9830967678	**280**	0.9824570403	**304**	0.9803970706	**328**	0.9791639481	**352**	0.9779370209
257	0.9830967678	**281**	0.9824570403	**305**	0.9803970706	**329**	0.9791639481	**353**	0.9779370209
258	0.9830967678	**282**	0.9824128485	**306**	0.9803970706	**330**	0.9791639481	**354**	0.9779370209
259	0.9830967678	**283**	0.9823232942	**307**	0.9803390799	**331**	0.9791001516	**355**	0.9778553245
260	0.9830967678	**284**	0.9823232942	**308**	0.9803390799	**332**	0.9791001516	**356**	0.9778553245
261	0.9830967678	**285**	0.9823232942	**309**	0.9803390799	**333**	0.9789346942	**357**	0.9778553245
262	0.9830516708	**286**	0.9823232942	**310**	0.9803390799	**334**	0.9789346942	**358**	0.9777099092
263	0.9830516708	**287**	0.9823232942	**311**	0.9803390799	**335**	0.9788174060	**359**	0.9777099092
264	0.9830516708	**288**	0.9823232942	**312**	0.9803390799	**336**	0.9788174060	**360**	0.9768812539
265	0.9830516708	**289**	0.9823232942	**313**	0.9803390799	**337**	0.9788174060	**361**	0.9768812539
266	0.9830516708	**290**	0.9823232942	**314**	0.9803390799	**338**	0.9788174060	**362**	0.9768812539
267	0.9830516708	**291**	0.9819156574	**315**	0.9802178676	**339**	0.9788174060	**363**	0.9767085255
268	0.9829597020	**292**	0.9818779459	**316**	0.9802178676	**340**	0.9788174060	**364**	0.9767085255

Table 10-12: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
0	1.0000000000	**48**	0.9818819454	**97**	0.9724145650	**146**	0.9651646731	**195**	0.9585852831
0	0.9989463518	**49**	0.9813940581	**98**	0.9724145650	**147**	0.9650179741	**196**	0.9585852831
1	0.9975582572	**50**	0.9811149797	**99**	0.9721278916	**148**	0.9650179741	**197**	0.9585106153
2	0.9968950221	**51**	0.9808357071	**100**	0.9719843820	**149**	0.9647244778	**198**	0.9583612369
3	0.9963635815	**52**	0.9804163818	**101**	0.9717688365	**150**	0.9646510762	**199**	0.9580621750
4	0.9954983869	**53**	0.9802065044	**102**	0.9716969486	**151**	0.9645042403	**200**	0.9580621750
5	0.9951651492	**54**	0.9801365116	**103**	0.9715531365	**152**	0.9643573707	**201**	0.9579873451
6	0.9945645668	**55**	0.9799264755	**104**	0.9713373330	**153**	0.9640634927	**202**	0.9579873451
7	0.9941636334	**56**	0.9796462096	**105**	0.9712653813	**154**	0.9638429283	**203**	0.9579125074
8	0.9939630137	**57**	0.9794358024	**106**	0.9711934225	**155**	0.9636958085	**204**	0.9577628083
9	0.9933601591	**58**	0.9790847785	**107**	0.9711214419	**156**	0.9634750547	**205**	0.9576130592
10	0.9931589002	**59**	0.9788739877	**108**	0.9710494372	**157**	0.9633278327	**206**	0.9575381540
11	0.9924871748	**60**	0.9787334069	**109**	0.9709774209	**158**	0.9631069028	**207**	0.9573882873
12	0.9923526429	**61**	0.9784520623	**110**	0.9707613132	**159**	0.9627384081	**208**	0.9573133332
13	0.9919487360	**62**	0.9783816832	**111**	0.9706892585	**160**	0.9625171483	**209**	0.9572383663
14	0.9916792045	**63**	0.9781704820	**112**	0.9706171946	**161**	0.9624433701	**210**	0.9571633895
15	0.9912068471	**64**	0.9781000588	**113**	0.9705451162	**162**	0.9622957853	**211**	0.9571633895
16	0.9905308509	**65**	0.9779591798	**114**	0.9704730247	**163**	0.9620743353	**212**	0.9569383725
17	0.9902600814	**66**	0.9778182436	**115**	0.9703288079	**164**	0.9619266457	**213**	0.9568633391
18	0.9899212765	**67**	0.9778182436	**116**	0.9699680182	**165**	0.9617049921	**214**	0.9567883006
19	0.9895819543	**68**	0.9775361418	**117**	0.9698236079	**166**	0.9616310727	**215**	0.9567132550
20	0.9895140131	**69**	0.9772537901	**118**	0.9696791597	**167**	0.9615571395	**216**	0.9566381918
21	0.9889017936	**70**	0.9770418835	**119**	0.9696069224	**168**	0.9614831983	**217**	0.9564880147
22	0.9882201168	**71**	0.9769712231	**120**	0.9693901236	**169**	0.9614831983	**218**	0.9562625865
23	0.9878104319	**72**	0.9769005466	**121**	0.9691008601	**170**	0.9614092449	**219**	0.9562625865
24	0.9874685977	**73**	0.9767590709	**122**	0.9689561390	**171**	0.9611132339	**220**	0.9561873965
25	0.9872633504	**74**	0.9765466782	**123**	0.9686665562	**172**	0.9611132339	**221**	0.9561121949
26	0.9870579950	**75**	0.9764758630	**124**	0.9685941382	**173**	0.9610391867	**222**	0.9560369867
27	0.9865784176	**76**	0.9761925132	**125**	0.9683767411	**174**	0.9609651281	**223**	0.9558865533
28	0.9863040866	**77**	0.9759089522	**126**	0.9681590825	**175**	0.9608910582	**224**	0.9557360679
29	0.9860295071	**78**	0.9757670435	**127**	0.9680864781	**176**	0.9607428635	**225**	0.9557360679
30	0.9859608276	**79**	0.9756250284	**128**	0.9678684348	**177**	0.9605945954	**226**	0.9557360679
31	0.9857547158	**80**	0.9754829371	**129**	0.9677956729	**178**	0.9604462255	**227**	0.9556608016
32	0.9854796626	**81**	0.9754829371	**130**	0.9675043666	**179**	0.9604462255	**228**	0.9556608016
33	0.9851355094	**82**	0.9754829371	**131**	0.9673585766	**180**	0.9603719931	**229**	0.9555102388
34	0.9849288641	**83**	0.9749850268	**132**	0.9671398110	**181**	0.9602977341	**230**	0.9555102388
35	0.9845152420	**84**	0.9749850268	**133**	0.9671398110	**182**	0.9601491697	**231**	0.9552089409
36	0.9844462708	**85**	0.9747001806	**134**	0.9669939177	**183**	0.9600748710	**232**	0.9552089409
37	0.9841701925	**86**	0.9747001806	**135**	0.9667019115	**184**	0.9598519074	**233**	0.9551335669
38	0.9838247337	**87**	0.9744152006	**136**	0.9664827327	**185**	0.9597775675	**234**	0.9549827718
39	0.9834789109	**88**	0.9739873157	**137**	0.9664827327	**186**	0.9597032090	**235**	0.9548319320
40	0.9832019349	**89**	0.9738445742	**138**	0.9664096522	**187**	0.9596288106	**236**	0.9546810412
41	0.9830633211	**90**	0.9736303735	**139**	0.9662634193	**188**	0.9595543795	**237**	0.9545300840
42	0.9828552725	**91**	0.9734160812	**140**	0.9661902639	**189**	0.9594799325	**238**	0.9544545732
43	0.9827164882	**92**	0.9734160812	**141**	0.9661902639	**190**	0.9592564778	**239**	0.9542279182
44	0.9825775890	**93**	0.9732016972	**142**	0.9659707159	**191**	0.9591074222	**240**	0.9542279182
45	0.9822995280	**94**	0.9730587142	**143**	0.9657510525	**192**	0.9590328768	**241**	0.9540767061
46	0.9821604041	**95**	0.9729156920	**144**	0.9656778054	**193**	0.9590328768	**242**	0.9540767061
47	0.9819515885	**96**	0.9726294362	**145**	0.9653113457	**194**	0.9587345577	**243**	0.9539254009

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Table 10-12: Baseline Post-Transplant Survival ($S_{TX}(t)$) Probability Where t=Time in Days (Continued)

t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$	t	$S_{TX}(t)$
244	0.9538497172	**269**	0.9511902217	**293**	0.9485888127	**317**	0.9463585089	**341**	0.9437285938
245	0.9538497172	**270**	0.9509612738	**294**	0.9483586281	**318**	0.9463585089	**342**	0.9436509982
246	0.9537740199	**271**	0.9506558210	**295**	0.9482818803	**319**	0.9462042511	**343**	0.9435733917
247	0.9537740199	**272**	0.9505794198	**296**	0.9481283428	**320**	0.9462042511	**344**	0.9434181618
248	0.9536983112	**273**	0.9504265693	**297**	0.9480515582	**321**	0.9461270863	**345**	0.9433405390
249	0.9536225901	**274**	0.9502736813	**298**	0.9479747621	**322**	0.9460499065	**346**	0.9431075841
250	0.9533952367	**275**	0.9501207590	**299**	0.9478210865	**323**	0.9460499065	**347**	0.9430298440
251	0.9533193886	**276**	0.9501207590	**300**	0.9476673351	**324**	0.9458955253	**348**	0.9430298440
252	0.9530158831	**277**	0.9498147874	**301**	0.9476673351	**325**	0.9458183199	**349**	0.9429520371
253	0.9530158831	**278**	0.9496617253	**302**	0.9473596856	**326**	0.9455866228	**350**	0.9427185272
254	0.9527122194	**279**	0.9496617253	**303**	0.9473596856	**327**	0.9454321012	**351**	0.9427185272
255	0.9527122194	**280**	0.9495851653	**304**	0.9473596856	**328**	0.9454321012	**352**	0.9427185272
256	0.9527122194	**281**	0.9495851653	**305**	0.9473596856	**329**	0.9453548209	**353**	0.9426406582
257	0.9524843651	**282**	0.9494319939	**306**	0.9472827362	**330**	0.9452775175	**354**	0.9424848995
258	0.9524083896	**283**	0.9493553886	**307**	0.9472827362	**331**	0.9451228653	**355**	0.9424848995
259	0.9523323977	**284**	0.9492787721	**308**	0.9472057776	**332**	0.9451228653	**356**	0.9421732641
260	0.9522563886	**285**	0.9492787721	**309**	0.9471288083	**333**	0.9449681796	**357**	0.9420173651
261	0.9521803676	**286**	0.9492021461	**310**	0.9469748345	**334**	0.9448908227	**358**	0.9417833903
262	0.9521043365	**287**	0.9492021461	**311**	0.9468208245	**335**	0.9447360580	**359**	0.9417053586
263	0.9518761834	**288**	0.9491255112	**312**	0.9468208245	**336**	0.9445812189	**360**	0.9416273052
264	0.9518000820	**289**	0.9490488687	**313**	0.9468208245	**337**	0.9445037758	**361**	0.9415492338
265	0.9516477499	**290**	0.9488955575	**314**	0.9467438071	**338**	0.9441938892	**362**	0.9415492338
266	0.9516477499	**291**	0.9488188902	**315**	0.9465897325	**339**	0.9440388525	**363**	0.9413148953
267	0.9515715365	**292**	0.9488188902	**316**	0.9464356005	**340**	0.9439613054	**364**	0.9413148953
268	0.9514952979								

History

Policy 3.7: Allocation of Thoracic Organs: 3/22/2007; 12/18/2007; 6/20/2008; 6/23/2009; 10/23/2009; 11/17/2009; 11/9/2010; 6/29/2011; 11/15/2011; 6/26/2012; 11/13/2012; 5/1/2013

Policy 10: Allocation of Lungs: 11/12/2013 (2/1/2014); 3/7/14; 06/23/14 (7/1/14); 11/12/14 (2/1/2015); 11/12/2012 (02/19/15); 11/12/2014 (02/19/15); *Policy 10: Allocation of Lungs:* 12/1/2015 (3/30/2017)

Notes

- For membership and personnel requirements for lung programs, see the *OPTN Bylaws, Appendix I*.

EXHIBIT B

Local Allocation of Lung Donors Results in Transplanting Lungs in Lower Priority Transplant Recipients

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Background. **Under the current lung allocation system, if organs are accepted for a candidate within the local donor service area (DSA), they are never offered to candidates at the broader *regional* level who are potentially more severely ill, even if the nonlocal candidate has a higher lung allocation score (LAS). The purpose of this study was to determine the frequency with which organs were allocated to a local lung recipient while a blood group–matched and size-matched candidate with a higher LAS existed in the same region.**

Methods. **United Network for Organ Sharing (UNOS) provided deidentified patient-level data. The study population included all locally allocated organs for double-lung transplants (DLTs) performed in 2009 in the United States (n = 580). All occurrences of an ABO blood group–matched, height-matched (± 10 cm), double-lung candidate in the same region, with a higher LAS than the local candidate who actually received the organs, were calculated; these occurrences were termed *events*.**

Results. **In 2009, 3,454 events occurred when a local DLT recipient candidate received a DLT while a DLT candidate in the same region had a higher LAS. With a mean of 5.96 events per transplant, this impacted 480 (82.8%) of the 580 DLTs. Further, 555 (16.1%) of these events involved 1 (or more) of the 185 regional candidates who ultimately did not receive transplants and died while on the waiting list.**

Conclusions. **This analysis suggests that the locally based lung allocation system results in a high frequency of events whereby an organ is allocated to a lower-priority candidate while an appropriately matched higher priority candidate exists regionally.**

(Ann Thorac Surg 2013;95:1231–5)

Given the disparity between potential recipients and available organs, efficient methods of organ allocation are needed to achieve maximal benefit from available organs. Our group has demonstrated in previous studies [1–4] that despite changes in the current lung allocation system, the following conditions exist: (1) high-priority lung transplantation candidates with lung allocation scores (LASs) of 75+ continue to die at high rates while on the transplant waiting list; (2) concurrently, more than four-fifths of lungs are allocated to low-priority candidates with an LAS less than 50; and (3) these low-priority recipients receive little net survival benefit from transplantation. These findings suggest that additional changes are needed to address the inefficiencies in the current lung allocation system and to maximize the benefit of organs available for transplantation.

More than a decade ago, the US Department of Health and Human Services (DHHS) issued the "Final Rule," which was intended to ensure that "allocation of scarce organs be based on common medical criteria, not accidents of geography" [5]. In 1998, the DHHS and Institute of Medicine (IOM) assembled an expert panel to assess the potential impact of the Final Rule on organ allocation in liver transplantation. The IOM analysis, which was completed in July 1999, concluded that "broader sharing of organs led to an overall increase in the rate at which the most severely ill patients were transplanted and a concomitant decrease in the excess transplantation of the least severely ill patients, without increasing pretransplantation mortality" [6]. More recently, in 2005, the Organ Procurement and Transplantation Network (OPTN) Lung Allocation Subcommittee recommended changes to the lung allocation policies "to minimize the effects of geography on waitlist outcome," in an effort to reduce waitlist mortality [7]. Despite the introduction of

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Abbreviations and Acronyms

DHHS = Department of Health and Human Services
dLAS = delta lung allocation score
DLT = double-lung transplant
DSA = donor service area
IOM = Institute of Medicine
LAS = lung allocation score
OPO = Organ Procurement Organization
OPTN = Organ Procurement and Transplantation Network
UNOS = United Network for Organ Sharing

the Final Rule, the findings of the IOM panel, and the recommendations of the OPTN, lung allocation remains a locally based system.

Under the locally based system, organs are initially offered only to the subset of appropriately matched lung transplantation candidates (based on blood group and size) within the donor's local donor service area (DSA). As a result, if an available organ is first accepted for a candidate within the local DSA, it is never offered at the broader regional or national level to candidates who are potentially more severely ill, even if the regional or national candidate has a much higher priority score.

The purpose of this study was to determine the frequency with which organs were allocated to a local lung recipient while there existed a blood group–matched, size-matched candidate with a higher LAS in the same region. We hypothesized that organs are frequently allocated to local candidates with lower LASs while regional candidates with higher LASs continue to die while awaiting transplantation.

Material and Methods

Data Collection

Use of data in this analysis was approved by the University of Chicago's Institutional Review Board (IRB) and is consistent with the regulations of the UNOS Data Use Agreement. The individual consent requirement was waived by the University of Chicago's IRB for this study because of the retroactive and deidentified nature of the data. The Standard Transplant Analysis and Research data set was provided by the United Network for Organ Sharing (UNOS (data source 01052011-6). UNOS provided deidentified patient-level data for all lung transplantation candidates and recipients in the United States. The data set contains information collected from the UNet^{SM} database forms, including the Transplant Candidate Registration Form, the Transplant Recipient Registration Form, and the Transplant Recipient Follow-up Form. These data sets are the basis for the UNOS Thoracic Registry.

This data set contains nearly 500 fields to characterize candidate/recipient and donor information, including demographics (eg, age, race, and sex), social history, and clinical information (eg, blood type, measures of lung function and hemodynamic measures, medical and surgical history, serologic test results, and severity of comorbid illness).

With special permission, UNOS provided supplemental data, including candidate listing/transplant center and candidate and donor organ procurement organization (OPO). In addition, UNOS provided data regarding interval changes in candidates' LAS while on the waiting list; an LAS for each candidate is typically provided for each day on the waiting list. This supplemental data totaled 2.5 million observations.

Study Population

The study group included lung transplant recipients who had an LAS, were aged ≥ 12 years, and received a double lung transplant (DLT) in 2009 (N = 580). Recipients who underwent simultaneous transplantation of another organ (n = 36) and those with missing LAS data (n = 15) were excluded from the analysis.

Data Analysis

All data were analyzed using the statistical software package, Stata 11 MP (Stata Corp, College Station, TX). Categorical variables were reported as counts and percentages. Continuous variables were reported as means.

Definitions

EVENT: All occurrences of an ABO blood group–matched, height-matched (± 10 cm), double-lung candidate in the same region with a higher LAS than the local candidate who actually received the organs.

DELTA LAS (DLAS): The difference between the LAS of the regional candidate who was bypassed, and the LAS of the candidate who actually received the organ.

PRIMARY OUTCOME: All occurrences of an ABO blood group–matched, height-matched (± 10 cm), double-lung candidate in the same region with a higher LAS than the local candidate who actually received the organs.

SECONDARY OUTCOMES: All occurrences of an ABO blood group–matched, height-matched (± 10 cm), double-lung candidate in the same region with an LAS 10, 25, or 50 points higher than the local candidate who actually received the organs. In addition, the number of events in which the candidate ultimately died on the waiting list was determined, as well as the number of discrete candidates bypassed who died.

Results

Study Population

In 2009, there were 580 locally allocated organs for DLTs in the United States. The mean LAS of transplanted local DLT recipients in this study was 42.5 ± 14.6.

Events

In 2009, 3,454 events occurred whereby a local DLT recipient candidate received a DLT while there was a DLT candidate in the same region with a higher LAS. With a mean of 5.96 events per transplant, this impacted

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Table 1. Study Group: Locally Allocated Double-Lungs[a]

Variable	Total Double-Lung Transplants Analyzed	No. of Events	Mean Events Per Transplant	No. of Transplants Involved	% of Transplants Involved	No. of Patients	No. of Patient Deaths	% of Patients Who Died
dLAS > 0	580	3,454	5.96	480	82.8	1,193	185	15.5
dLAS > 10	580	828	1.43	320	55.2	333	91	27.3
dLAS > 25	580	250	0.43	170	29.3	111	41	36.9
dLAS > 50	580	63	0.11	48	8.3	41	19	46.3

[a] Analysis of all 580 locally allocated organs for double-lung transplantation in 2009 in the United States based on ABO blood group–matched, height-matched (± 10 cm), double-lung candidates in the same region who had a higher LAS than the local candidate who actually received the transplant.

dLAS = delta lung allocation score; LAS = lung allocation score.

480 (82.8%) of the 580 DLTs. Among these, 828 had a dLAS greater than 10, 250 had a dLAS greater than 25, and 63 had a dLAS greater than 50.

Differences in LAS of greater than 10, greater than 25, and greater than 50 affected 320 (55.2%) transplants, 170 transplants (29.31%), and 48 transplants (8.28%), respectively. The mean number of events per transplant with differences in LAS of greater than 10, greater than 25, and greater than 50 were 1.43, 0.43, and 0.11, respectively (Table 1).

Related Deaths

In total, 555 (16.1%) of these events involved a regional candidate who did not receive a transplant and ultimately died while on the waiting list, including 185 separate candidates. Among these deaths, 91 were in regional candidates with a dLAS greater than 10, 41 in candidates with a dLAS greater than 25, and 19 in candidates with a dLAS greater than 50 (Table 1).

Comment

This analysis suggests that organs are commonly allocated to local candidates with a lower LAS while regional candidates with a higher LAS continue to wait and/or die without the benefit of transplantation. The study further reveals that 185 separate candidates who were bypassed in favor of local candidates with a lower LAS ultimately died while waiting.

Waiting List Outcomes

In previous studies [1–4], our group demonstrated that despite recent changes in the lung allocation system, inefficiencies persist in the current system. First, since the initiation of the LAS in 2005, more than 80% of donor lungs were allocated to low-priority candidates (LAS < 50). Differences in LAS have a clinically meaningful relationship with survival on the waiting list in the absence of transplantation. Based on our previous analysis of survival on the waiting list in the absence of transplantation, waiting list survival among patients with an LAS less than 50 is approximately 4 years, those with an LAS 50 to 74 is approximately 6 months, and those with an LAS 75+ is less than 30 days.

These findings are particularly troublesome because low-priority candidates rarely die while awaiting transplantation. In fact, in a previous study, our group demonstrated that at 1 year follow-up, less than 10% of candidates with an LAS less than 50 die on the waiting list. More significantly, low-priority candidates appear to receive little or no net survival benefit from transplantation [2, 9]. Based on these findings, we concluded that additional changes are needed to address the inefficiencies of the current lung allocation system and to maximize the benefit of organs available for transplantation. These inefficiencies may result, in part, because of the locally based allocation system, which results in a higher allocation of organs to candidates with less urgent needs.

Local Geographic Units

The local geographic units for lung transplantation consist of 58 DSAs in the United States and Puerto Rico. The OPOs are responsible for obtaining and allocating organs for transplantation within the DSAs. DSAs and OPOs lack standardization. Most notably, the populations of DSAs differ by nearly 20-fold, ranging from 1.3 million to 18.7 million, and organ recovery practices vary significantly across OPOs [8]. Therefore, it should not be surprising that there is wide variability across OPOs in performance measures, including donor consent rates, conversion rate of candidates to organ donors, organs procured per donor, and candidate wait times [8].

Limitations

This study has several limitations. First, patient registries often suffer from data entry variability. However fields contained within this database were generally well populated with a 95% to 99% data entry rate for the majority of variables. Second, although the UNOS reporting system provided variable definitions in data guidelines, definitions may still differ by center. Third, this analysis was retrospective. Although the data analysis supports associations between variables and outcomes, causal relationships cannot be determined. Fourth, information regarding why organs were declined for a candidate was not available. Fifth, some clinicians and policymakers have expressed concern that broader organ sharing will lead to lower donation rates because the potential donors may prefer to have members of their local community benefit from their donation. With the available data, this study cannot evaluate the impact of broader organ sharing on donation rates. However in its evaluation of this issue, the IOM panel found "little or no

evidence to support the assertion that people would decline to donate . . . if they knew a donated organ would be used outside the donor's immediate geographic area" [6]. Sixth, to simplify the analysis, DSAs and regions, rather than distances, were used to define geography. In the UNOS data, there was not sufficient demographic information related to the donor hospital to reliably calculate distance between donor and transplantation center. Finally, because this study considers only double-lung candidates, does not consider national matches, and does not allow for blood groups to be crossed, it likely underestimates the frequency of these events and the number of lives lost.

Implications and Future Studies

With the current system of prioritizing local candidates over potentially higher priority regional candidates, this study suggests that high-priority lung candidates are dying unnecessarily while waiting for donor lungs. Such findings are even more troubling because it appears that lower priority candidates receive little or no net survival benefit from transplantation [2]. Combined with the results of the IOM panel researching broader organ allocation in liver transplantation, these studies suggest that organ sharing over a broader geographic area would increase the net survival benefit of lung transplantation.

Two potential improvements to the current policy include (1) allocating organs over a larger geographic area (eg, 250 or 500 miles) based on LAS, rather than limiting priority to local candidates or (2) using a system similar to the system for heart transplantation in which organs are preferentially allocated to high-priority (eg, LAS 75+) candidates locally, then high-priority candidates over a broader geographic area (eg, regionally or over a 250–500 mile radius), then intermediate-priority (eg, LAS 50–74) candidates locally, then intermediate-priority candidates over a broader geographic region, then low-priority (eg, LAS $<$ 50) candidates locally, and then low-priority candidates over a broader geographic region.

Our group is undertaking further studies to replicate the analysis performed by the IOM group to test the central hypothesis that organ sharing over broader geographic areas would result in better allocation of organs as measured by higher rates of organ allocation to higher priority candidates, improved survival on the waiting list among lung transplantation candidates, and an increased net benefit of transplantation.

Conclusions

Findings from this analysis suggest that the locally based allocation system results in a high frequency of events whereby an organ is allocated to a lower priority candidate while an appropriately matched higher priority candidate exists regionally. This may result unnecessarily in the death of higher priority candidates, thus diminishing waiting list outcomes and the net benefit of transplantation. Additional changes to the lung allocation system are needed to maximize the currently available pool of organs for transplantation.

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DISCUSSION

DR THOMAS EGAN (Chapel Hill, NC): Congratulations on finally providing some data. You'll see when I get up and talk about a national allocation system that there is virtually no data in the literature to argue in favor of more widespread distribution.

I was curious why you used UNOS regions, which are just as foolish as OPOs in some respects because of the huge difference in size of the regions.

DR RUSSO: Sure. It's simple. There was essentially 2 ways to do this, 1 was to use the regions, the other way would be to use a mapping program that would actually map where the candidates were. So what you're basically suggesting is, should it be a 200- or 500-mile radius around which the organs are allocated, and I happen to agree with you that the boundaries don't make any sense, as we showed in our clinical scenario, where the patient was 20 miles from the donor hospital but outside of the local DSA. It was basically to simplify the analysis in short.

DR DAVID MASON (Cleveland, OH): I thought that was really a fascinating talk and a lot of work to try to get to an answer, and sometimes the answer takes a lot of complicated work. Honestly, I got lost a bit along the way.

What is your recommendation? Do you have an idea of what changes you would like to see? It seems like there are always

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going to be lines drawn. There is an eastern time zone, there's a central time zone, and you live across the time zone, your clock is different, unfortunately. It seems there will need to be certain lines that need to be drawn.

DR RUSSO: Well, I think that heart transplant offers a reasonable model to do this where patients who are 1A and 1B are allocated first. So whether the patient is regional or local, it goes to the highest priority patient—well, I'm sorry, it goes to the 1A or 1B local. If that doesn't exist, then it goes to the 1A or 1B regional, and then it only goes to a 2 local if there is no 1A or 1B within a 500-mile radius, so it's not within the regions. I think that that's a reasonable mechanism. I think the way that you would adopt that to LAS is to define ranges, and I don't know if these are the best, but the most simplistic ranges would be to say between 25 and 50, between 50 and 75, and between 75 and 100.

Actually in some of the previous work that we've done, we've been able to show that if you look at the patients who are between LAS of 25 and 50, their survival is generally estimated, in the absence of transplant, in terms of years; patients between 50 and 75, it's months, and then patients greater than 75, it's weeks to days. So there is actually some clinical data I think to support that, but I think that having an LAS range that's analogous to the 1A, 1B, 2 system I think makes a lot of sense.

DR STEPHEN CASSIVI (Rochester, MN): I'm just rising to congratulate you on also putting some data to a problem that we all know is there. I mean, we face different geographic boundaries at election time, but more blatantly, and it affects probably more lives when we face them at the time of transplant. It's just ridiculous that the geographic or political boundaries of one state versus another means that one person gets denied an organ that would likely go to them if it was in a proper allocation system.

I would argue to you that we currently have computer systems—and you've clearly got some matrices there that are quite complex to do the research you've done—but we've got computers now that can easily map out 250-mile or 300-mile or 500-mile radii that at the time of allocation could be instituted, and maybe in the era of an evolving ex vivo, or whatever, perfusion model, we can extend the ischemic time such that we can really wipe out some of these boundaries. It would be appropriate to get the right patients transplanted at the right time.

DR RUSSO: Two comments on that. In some of our previous work we showed that probably about, I think it's 83% of patients who are transplanted have LAS scores of less than 50, whereas a very small percentage of patients with much higher scores are transplanted. That would be fine if the higher score patients weren't dying on the list, but they in fact are.

The second thing that I would say is, I think that it would be great if we could have better preservation systems, but quite honestly, an hour or another 90 minutes of cold ischemic time for a lung probably doesn't negatively impact long-term survival in a meaningful way that would support this continued allocation system.

DR SETH FORCE (Atlanta, GA): That was a fantastic talk. I'm just going to be the devil's advocate here and take the con side.

I think it's a great system. I think 1 concern, or a couple concerns that you have to decide how you're going to deal with patients who are presensitized and may have a low to medium LAS score and may sit on the list for a long time, losing local donors, where they need a prospective crossmatch, to outside recipients.

The other thing to be concerned about are smaller programs that are close to dominant huge programs, and where those programs are gobbling up so many of the donors that the smaller programs around actually may cease to exist in a program like that. Then you've got a lot of recipients who, unlike kidney and liver transplant, can't travel and there actually is no longer a local program there.

So I think that I agree with you in principle that it's ridiculous that a 27-year-old CF patient died while a 70-year-old, or whatever, got lungs. But I think we do have to be careful about how a new system is created and how it's going to affect the local programs also.

DR RUSSO: I agree. You know, I think that I skipped past this slide, for whatever reason, but 1 of the things that's worth pointing out here is going back to the clinical scenario, if I can get there, is here it's not just that there is 1 or 2 patients who had higher scores, there's actually—in just this screen shot alone, there are 16 patients who had higher scores than the people who ultimately got transplanted, the number may be longer because that's where the screen shot ends. So I would say that all of those other scenarios, I mean given the number of patients that are involved in these scenarios, I'm not sure that that's a reason not to move forward.

As far as the smaller programs go, it definitely is a concern, but in the liver transplant, the IOM study looking at liver transplant, that turned out not to be true.

The other concern is for patients who are socioeconomically disadvantaged, the concern was that they would be transplanted at lower rates, and the models don't suggest that that's true. Those are things that a model doesn't necessarily prove but can be tested for.

EXHIBIT C

Clin Transplant 2016: 30: 688–693 DOI: 10.1111/ctr.12735

Clinical Transplantation

Distribution of donor lungs in the United States: a case for broader geographic sharing

Iribarne A, Meltzer DO, Chauhan D, Sonett JR, Gibbons RD, Vigneswaran W, Russo MJ. Distribution of donor lungs in the United States: a case for broader geographic sharing.

Abstract: Objectives: To evaluate the association between allocation of donor lungs by geographic sharing type (GST) and lung allocation score (LAS).
Methods: UNOS data included lung transplant recipients between 5/4/05 and 09/30/15 (n = 17 416) grouped by GST of donor lungs: local, regional, or national. Recipients were stratified by LAS <50, 50–75, and >75. Kaplan–Meier analysis was used to assess five-yr survival.
Results: The majority of lungs were shared locally (n = 9200; 52.8%) followed by nationally (n = 5356; 30.8%) and regionally (n = 2860; 16.4%). There was a significant difference in the mean LAS at transplant (local: 43.7 ± 15; regional: 49.5 ± 18.8; national 51 ± 19.4; $p < 0.001$). There was a significant association between GST and LAS ($p < 0.001$). The majority (n = 7431; 58.2%) of recipients with LAS <50 received local lungs. Recipients with LAS >75 received a majority of their organs from national (n = 881; 45.4%) and regional (n = 414; 21.6%) donors. Although statistically significant ($p = 0.024$), absolute decline in five-yr survival by GST in the national GST was only 1.1% compared to the local GST.
Conclusions: Nearly half of all lungs in the United States are allocated locally to recipients with an LAS <50. Additional studies should determine if organ sharing over broader geographies would improve waitlist outcomes.

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Key words: donor lung – geographical distribution – lung allocation score – lung transplant – United States

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Current organ procurement, allocation, and transplantation practices in the United States, are complex and based on geographic boundaries defined by the United Network for Organ Sharing (UNOS). Organ allocation can be local, regional, or national. In most instances, the local unit is the Organ Procurement Organization (OPO) in that area. The OPO is accepted as a member of UNOS and is authorized by the Health Care Financing Administration (HCFA) to procure organs for transplantation. For each OPO, the HCFA defines a geographic procurement territory within which the OPO concentrates its efforts. This territory usually encompasses several miles from the organ procurement hospital. A region, on the other hand, comprises four or five states including and around the state in which the organ is procured. Currently, the United States is divided in 11 geographic regions to facilitate organ transplantation. If there is no suitable recipient for the donor, the organ is allocated beyond regions and can be allocated nationally, meaning anywhere in the United States. (1)

Given the disparity between potential recipients and available donors, efficient methods of organ allocation are needed to achieve maximal benefit from existing organs. In an effort to reduce waitlist mortality, the Organ Procurement and Transplantation Network (OPTN) Lung Allocation Subcommit-

tee recommended two significant changes in lung allocation policies in 1998: (i) to allocate organs based on medical urgency and (ii) to minimize the effects of geography on waitlist outcome (2).

In response to the Subcommittee's request, the Lung Allocation Score (LAS) was implemented in May 2005 to allocate organs based on predicted net survival benefit of transplantation. The LAS is calculated based on a multivariable model that is a weighted combination of predicted survival on the waitlist for one yr and predicted post-transplant survival at one yr (3). Since the introduction of the LAS, favorable trends in waitlist times and waitlist mortality have been observed (4–7). However, findings from our group suggest that even within the LAS-era, a high proportion of organs are being allocated to low-priority candidates, while candidates with a higher LAS continue to die at high rates on the waitlist (8).

These observed inefficiencies in organ sharing may be in part due to the locally based allocation structure. The importance of geography on waitlist outcomes in transplantation has been well recognized (1). Under the current "local" lung allocation system, available organs are initially offered only to the subset of appropriately matched transplant candidates (based on blood group and size) within the donor's local geographic unit, known as the donor service area (DSA). If an available organ is first accepted for a candidate within the local DSA, it is never offered to potentially more severely ill candidates at the broader regional or national level, even if the non-local candidate has a higher LAS. The purpose of this study was to describe the allocation of donor lungs by geographic sharing type (GST) (local, regional, or national) and LAS at time of transplant.

Materials and methods

Data collection

The Standard Transplant Analysis and Research Dataset was provided by UNOS (data source #010311-3). The dataset contains information collected from the UNet^{SM} database forms, including the Transplant Candidate Registration form, the Transplant Recipient Registration form, and the Transplant Recipient Follow-up form. These data are the basis for the UNOS Thoracic Registry.

Study population

UNOS provided de-identified patient-level data for all lung transplant candidates and recipients in the United States. Use of these data is consistent with the regulations of our university's institutional review board and the UNOS Data Use Agreement. The analysis included lung transplant recipients aged ≥12 yr old and listed between May 4, 2005 and September 30, 2015 (n = 17 416). Follow-up data were provided through December 3, 2015. Patients were followed from the date of listing until death, transplantation, re-transplantation, or date of last known follow-up provided by UNOS. Recipients who underwent simultaneous transplantation of another organ (n = 91) and those with missing LAS data (n = 432) were excluded from the analysis.

To study the effect of geography on waitlist outcomes, GST was categorized using data supplied by UNOS as: local (within the OPO), regional (outside of the OPO, but within the same sharing region), or national (outside of the sharing region). Patients were also stratified into three groups based on LAS at the time of transplant. The categorization of LAS was based on previously defined LAS thresholds (8, 9): <50 ("low priority"), 50–75 ("intermediate priority"), >75 ("high priority").

Data analysis

All data were analyzed using the statistical software package, Stata 14 (Stata Corp, College Station, TX, USA). Continuous variables were reported as means and categorical variables reported as frequencies. Continuous variables were compared using the Student's *t*-test, while categorical variables were compared using the chi-square test. The analysis of variance (ANOVA) test was utilized to compare means between GST and LAS categories. The univariate log-rank test for equality of survivor functions was used for survival analysis. The conventional p-value of 0.05 or less was used to determine the level of statistical significance. All reported p-values are two-sided.

The primary analysis reports the distribution of donor lungs by GST and LAS category. The secondary analysis examines post-transplant graft survival by GST. For post-transplant graft survival, recipients were followed from date of transplant to graft failure (defined by patient death or re-transplantation) or last known follow-up. The outcome of interest was graft loss. Candidates were censored as either lost or alive at last known follow-up.

Results

Patient characteristics

From May 4, 2005 to September 30, 2015, there was a total of 17 421 lung transplant recipients in

the United States. The GST was distributed as follows: local, n = 9200; regional, n = 2860; and national, n = 5356. Five organs were transplanted outside the United States, and they were excluded. Baseline characteristics of the three groups, in addition to select recipient characteristics, are shown in Table 1.

Geographic distribution of organs

The distribution of donor lungs by GST and recipient LAS category is shown in Fig. 1. Using the ANOVA test, we found that there was a significant association between broader geographic sharing and higher LAS at the time of transplant ($p < 0.001$). While 80.77% (n = 7431) of local organs were allocated to recipients with LAS <50, this proportion decreased to 63.77% (n = 3416) for national donors. Conversely, 7% (n = 644) of local organs were allocated to recipients with LAS >75, but this proportion increased to 16.45% (n = 881) for national donors. There was a significant difference in the mean LAS at the time of transplant between the three GSTs (local: 43.7 ± 15; regional: 49.5 ± 18.8; national 51 ± 19.4; $p < 0.001$), with the highest mean LAS in the national sharing group and the lowest mean LAS in the local sharing group.

Outcomes by geographic region

Post-transplant survival stratified by GST is shown in Fig. 2. The difference in survival across GST approached statistical significance ($p = 0.024$). At 90 d, survival rates for local, regional, and national groups were 93.8%, 93.6%, and 92.7%, respectively. At one yr, survival rates for local, regional, and national groups were 85.7%, 84.7%, and 83.8%; at five yr 54.2%, 51.6%, and 53.1%; and at 10 yr 27.1%, 27.5%, and 29.6%, respectively. At five yr post-transplantation, there was only a 1.1% difference in survival between local and national groups.

Discussion

The results of this analysis demonstrate that within the locally based lung allocation system, close to half of donor lungs go to patients with an LAS <50 and, in instances of broader geographical sharing, that proportion decreases. These observations highlight two potential shortcomings of the current allocation system: (i) low-priority patients may be receiving a disproportional share of donor organs and (ii) geography may have a significant influence on waitlist outcomes.

Instances where low-priority patients (i.e., LAS <50) are being transplanted over high-priority patients (i.e., LAS >75), potentially on the basis of geography, are concerning because low-priority patients receive little or no net survival benefit from transplantation (8). While patients with LAS <50 have a mean survival in the absence of transplantation measured in years, patients with LAS >75 have a mean survival in the absence of transplantation measured in days. Annually, hundreds of lung transplant candidates die on the waitlist, with more than 60% of them being high-priority candidates (8), despite high-priority candidates representing less than 10% of all candidates listed for lung transplantation (8). The results of our analysis show that broader geographic allocation of donor lungs may result in an increase in the proportion of high-priority candidates being transplanted.

Local allocation does more to influence transplantation outcomes than increase the proportion of low-priority recipients. There are also substantial disparities in both the structure and clinical outcomes of donor service areas (DSAs), the local allocation region. DSAs vary in size from a few counties to multi-state complexes (10). The total population served by each DSA varies more than 10-fold, from approximately 1 300 000–18 700 000 people. Further, each DSA is overseen by an independent managing organization, known as an OPO. Each OPO has different policies and

Table 1. Baseline characteristics stratified by geographic region

Baseline variable	Local N = 9195	Regional N = 2860	National N = 5356	p-Value
Donor age in years (mean ± SD)	33.33 ± 13.8	34.75 ± 14.5	35.19 ± 15.0	<0.001
Ischemic time in hours (mean ± SD)	4.6 ± 1.6	5.3 ± 1.6	6 ± 1.7	<0.001
Donor IDDM	549 (6%)	192 (6.7%)	411 (7.7%)	<0.001
Donor pulmonary infection	4672 (50.8%)	1428 (49.9%)	2502 (46.7%)	<0.001
Recipient on ECMO	148 (1.6%)	94 (3.3%)	211 (3.9%)	<0.001
Recipient intubated	432 (4.9%)	245 (9.4%)	563 (11.7%)	<0.001

ECMO, extracorporeal membrane oxygenation; IDDM, insulin-dependent diabetes mellitus.

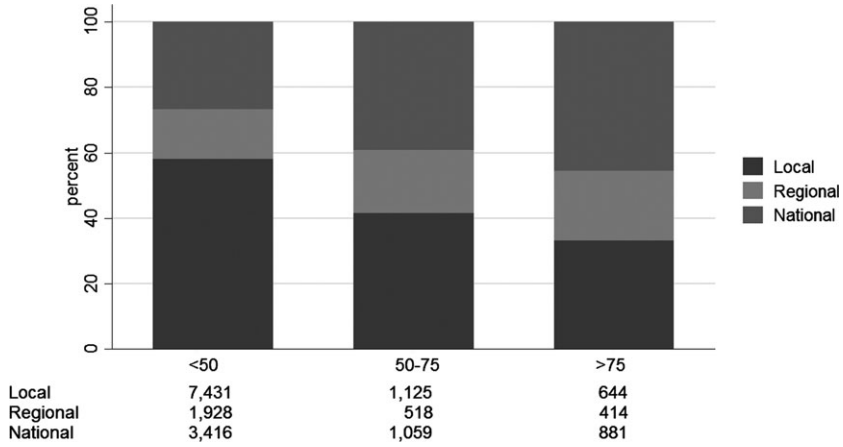

Fig. 1. Distribution of donor lungs by geographic region and lung allocation score category of recipient.

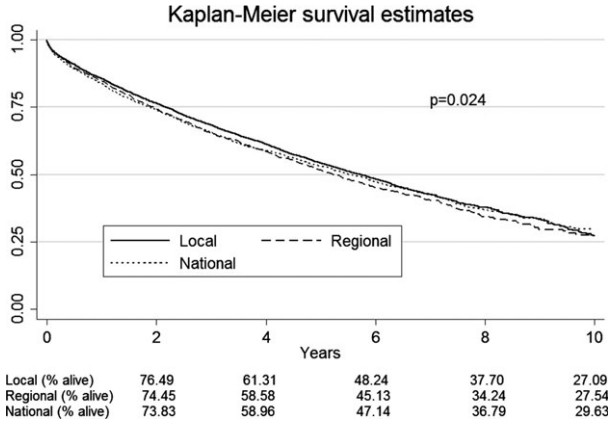

Fig. 2. Post-transplant survival stratified by geographic region of donor organ.

practices to accommodate local preferences, contributing to significant procedural and performance measure variation across OPOs (11): the number of eligible donors reported, total donors recovered, and the total number of organs transplanted vary from 15- to 25-fold. This dramatic variability translates into disparities in outcomes for transplant candidates depending on where they reside.

A common argument made against broader organ sharing is that longer ischemic times will lead to lower post-transplant survival. However, this was not observed in our analysis. As demonstrated in Fig. 2, there was no clinically significant difference in survival when stratified by GST. For example, at five yr post-transplantation there was only a 1.1% difference in survival between local and national groups. This finding was observed despite the higher percentage of high-priority recipients in the broader sharing groups (i.e., regional and national). Another common argument is that broader organ sharing would decrease transplantation for local candidates, particularly economically disadvantaged patients (12). However, in models for broader allocation practices in liver transplantation, previous groups found no evidence that minorities and economically disadvantaged patients are at a disadvantage in a broader allocation system (13).

In 1998, the US Department of Health and Human Services (DHHS) issued the "Final Rule" declaring that, "organs be [allocated] based on common medical criteria, not accidents of geography" (9). Subsequently, the DHHS and Institute of Medicine (IOM) assembled an expert panel to assess the impact of geography on organ allocation and waitlist outcomes in liver transplantation. The IOM panel concluded that "broader sharing of organs led to an overall increase in the rate at which the most severely ill patients were transplanted and a concomitant decrease in the excess transplantation of the least severely ill patients, without increasing pre-transplantation mortality" (1). Despite the introduction of the "Final Rule" and the findings of the IOM panel, no significant policy change has been adopted to minimize the impact of geography on the allocation of donor lungs.

The organ transplant community still follows many guidelines for donor selection and organ allocation which are based on expert opinions and are not data driven. These criteria if strictly followed lead to an overall smaller number of organs transplanted and/or inefficient distribution of organs as well as an overall suboptimal organ utilization. There is an ever increasing body of evidence promoting revisions and changes in these guidelines. Reyes et al. (14) showed that even though in more than half of lung transplant cases at least one of the donor selection guidelines was not followed, there was no difference in clinical outcome in lung transplant patients. Speicher et al. reported that among donors for single lung transplant (SLT), less than half of the cases led to use of

the second donor lung. Independent predictors of non-utilization included ABO incompatibility and lower body surface area. The authors suggested that UNOS should consider requiring OPOs to more aggressively place both lungs for SLT including placing the other lung outside the LAS system (15). Ware et al. (16) performed an analysis of rejected donor lungs by conventional criteria and found that 41% of those organs could be utilized if prospectively defined criteria by the California Transplant Donor Network were used.

Limitations

These data have several limitations. First, large patient registries often suffer from incompleteness in data entry. Fields contained within this database, however, were well populated with a 90–99% data entry rate for the majority of variables. Patients with missing LAS data (n = 15) were not included in the analysis; however, given the large sample size (n = 17 416), it is unlikely that these excluded patients would have significantly altered the results.

Second, the stratification of the study population by LAS into low, medium, and high-priority recipients is not based on clinical set-points. Nonetheless, the differences in clinical profiles of patients with LAS <50, LAS 50–75, and LAS >75 are clinically meaningful, and other studies have used these thresholds, after demonstrating that waitlist mortality increases in a stepwise fashion with each 10 point increase in LAS (8).

Finally, the survival analysis by GST does not adjust for baseline differences between groups. Therefore, causal relationships between GST and post-transplant survival cannot be determined.

Implications

This analysis provides evidence that broader geographical sharing of lungs may result in an increased percentage of high-priority lung recipients. In an effort to identify mechanisms to further improve the lung allocation system and therefore increase the survival benefit from transplantation, our future research agenda includes a series of analyses intended to explore the impact of local allocation of organs on waitlist outcomes. By adapting statistical methods applied by an IOM panel assembled by the DHHS (1) to explore similar questions in liver transplantation, this proposal will use mixed-effects multinomial logistic regression analysis to test the central hypothesis that organ sharing over broader geographies would result in better allocation of organs as measured by:

1. Higher rates of organ allocation to higher priority candidates
2. Improved survival on the waiting list among lung transplant candidates
3. Increased total net survival benefit of transplantation aggregated across all lung transplant candidates.

If findings of this analysis support the primary hypothesis, this study will provide important evidence to support changes in the lung allocation policy, namely that organs over broader geographies will increase the net survival benefit of transplantation.

Authors' contributions

Alexander Iribarne: Concept, Manuscript writing, Statistical analysis; David Meltzer: Critical revision of the paper; Joshua Sonett: Research design, interpretation of data; Dhaval Chauhan: Drafting the paper and revising it critically; Robert Gibbons: Statistical analysis, interpretation of results; Wicki Vigneswaran: Approval of final versions; Mark Russo: Research design, concept and approval of final versions.

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